EPA Registration No. 7173-286 vol. 2

LIPHATECH

3600 WEST ELM STREET
MILWAUKEE, WI 53209
Tel: 414/351 1476 800/351 1476
Fax: 414/247 8166

U.S. Environmental Protection Agency
Document Processing Desk
Office of Pesticide Programs (7504P)
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

Attn: John Hebert, Insecticide-Rodenticide Branch

March 27, 2013

Re: Report of Rozol Prairie Dog Bait, EPA Reg. No. 7173-286 sales to satisfy PRM3

Dear Mr. Hebert,

The attached table provides the first year of a five year reporting requirement regarding the sales of Rozol Prairie Dog Bait, EPA Reg. No. 7173-286. The requirement of Liphatech, Inc. and EPA to report sales by state of this product, to the FSW, comes from the Rozol Biological Opinion. The attached table represents Liphatech's sales to distributor's original ship to locations. Distributors sell in multiple prairie dog states and ship product based on end user demand to these locations, therefore, exact reporting of end use location is not possible.

The information provided in this report is meant to be forwarded to FWS and is classified as **Confidential Business Information**.

Please contact me directly if there is any further question or action needed on the part of Liphatech, Inc.

Sincerely,

Michele Brunlinger
Compliance Specialist
(414) 410-7235 phone

Claimed confidential by submitter

United States Department of the Interior

FISH AND WILDLIFE SERVICE
Mountain-Prairie Region

IN REPLY REFER TO:
FWS/R6
ES

MAILING ADDRESS:
P.O. BOX 25486, DFC
Denver, Colorado 80225-0486

STREET LOCATION:
134 Union Boulevard
Lakewood, Colorado 80228-1807

APR 09 2012

Ms. Anita Pease
U.S. Environmental Protection Agency
Office of Pesticide Programs, Ariel Rios Bldg.
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Ms. Pease:

This document transmits the U.S. Fish and Wildlife Service's (FWS') final Biological Opinion (BO) for the proposed use of Rozol® Prairie Dog Bait, a product registered under the Federal Insecticide, Fungicide and Rodenticide Act of 1947, as amended (7 U.S.C. §136 et seq.).

The Environmental Protection Agency (EPA) determined that 21 federally listed could be adversely affected by the proposed action and initiated formal Section 7 consultation with the Service (EPA 2010b). The formal consultation process revealed that adverse effects for numerous federally listed species are not anticipated and adverse impacts to other listed species have been minimized or eliminated as a result of the EPA's adoption of conservation measures.

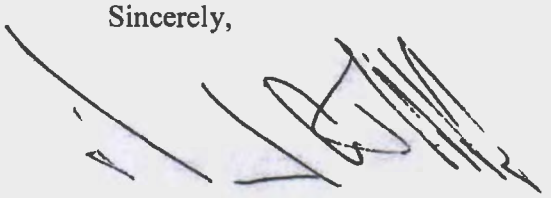
Incidental take is anticipated to occur as a result of the proposed action for the black-footed ferret, gray wolf, and northern aplomado falcon and is addressed in the Incidental Take Statements (ITS). The ITS contains nondiscretionary Reasonable and Prudent Measures (RPMs) with implementing Terms and Conditions (TCs) designed to reduce the potential for take of the black-footed ferret, gray wolf, and northern aplomado falcon. Among the RPMs and TCs are monitoring and reporting requirements necessary to determine if the RPMs and TCs are functioning as intended, whether take is exceeded, or if unanticipated take of other listed species occurs. Please see the Reinitiation Notice near the end of the document for additional information about reinitiation.

The Service and other conservation organizations have previously expressed many concerns to the EPA regarding use of anticoagulant prairie dog rodenticides and the subsequent exposure and adverse effects to wildlife (Nebraska Game and Parks Commission 2006; Koch 2008; Lanka 2009; Lloyd 2009; Mann 2009a, 2009b; Service 2006a, 2006e, 2007c, 2009h). The Service and States, as natural resource trustees, are directed to protect wildlife, as is the EPA under their authorities for pesticide use and registration. This BO identifies measures and actions that can reduce and mitigate potentially harmful exposures to species federally listed under the Endangered Species Act (Act).

The current Rozol label and registration requirements are inadequate for addressing Migratory Bird Treaty Act and Bald and Golden Eagle Protection Act bird deaths that have previously occurred from Rozol use on prairie dogs and that are expected to continue under the proposed action. The registration of Rozol should be accompanied with detailed monitoring and field studies to abate Rozol secondary exposure and effects to raptors and other non-target animals. The Service requests that our agencies work together to identify and implement measures to address these non-ESA concerns that involve secondary poisoning of raptors from exposure to anticoagulant prairie dog rodenticides.

This BO is based on the EPA's Biological Assessment posted online by the EPA, items identified in the "References Cited" section herein, various conference calls and meetings regarding this action, and other sources of information. A complete record of this consultation is on file at the Service's South Dakota Ecological Services Office in Pierre, South Dakota. If any questions arise regarding this BO, please contact Scott Larson of the Service's South Dakota Ecological Services Office at (605) 224-8693, Extension 224, or at 420 South Garfield Avenue, Suite 400, Pierre, South Dakota 57501.

Sincerely,



Michael Thabault
Assistant Regional Director
Ecological Services

Final Biological Opinion
For Rozol Use on Black-tailed Prairie Dogs
Registered Under Section 3 of the
Federal Insecticide, Fungicide and Rodenticide Act

Photo Credit: U.S. Fish and Wildlife Service

Prepared by:

U.S. Fish and Wildlife Service
Ecological Services Region 6 and Region 2

April 9, 2012

TABLE OF CONTENTS

ACRONYMS AND ABBREVIATIONS

AOK	Audubon of Kansas
BA	Biological Assessment
BO	Biological Opinion
BTPD	Black-tailed prairie dog
CPW	Colorado Division of Parks and Wildlife
CFR	Code of Federal Regulations
DDE	dichlorodiphenyldichloroethylene
DDT	dichlorodiphenyltrichloroethane
DOW	Defenders of Wildlife
DPS	Distinct Population Segment
EEC	Estimated Environmental Concentration
EPA	U.S. Environmental Protection Agency
ESA	Endangered Species Act
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
GPS	Global Positioning System
IPM	Integrated Pest Management
ITS	Incidental Take Statement
LC_{50}	Lethal Concentration
LD_{50}	Lethal Dose
LOC	Level of Concern
MBTA	Migratory Bird Treaty Act
MRID	Master Record Identification
NDA	Nebraska Department of Agriculture
NEP	Nonessential Experimental Population
PCE	Primary Constituent Element
PMJM	Preble's meadow jumping mouse
RPA	Reasonable and Prudent Alternative
RPM	Reasonable and Prudent Measure
RQ	Risk Quotient
Service/FWS	U.S. Fish and Wildlife Service
SLN	Special Local Needs
TRV	Toxicity Reference Value
USC	U.S. Code
USCOE	U.S. Corps of Engineers
USDC	U.S. District Court of Columbia
USDOI	U.S. Department of the Interior
USGS	U.S. Geological Services
WAFWA	Western Association of Fish and Wildlife Agencies
WWF	World Wildlife Fund
WYNDD	Wyoming Natural Diversity Database

BIOLOGICAL OPINION

I. INTRODUCTION

Section 7(a)(2) of the Endangered Species Act (ESA) of 1973, as amended (16 U.S.C. 1531 et seq.) requires that:

> "*Each Federal agency shall, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out . . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species. . . . In fulfilling the requirement of this paragraph each agency shall use the best scientific and commercial data available.*"
> 16 U.S.C. § 1536(a)(2)

To meet this standard, when a Federal agency determines that its proposed action may affect a listed species or critical habitat, it enters into consultation with the U.S. Fish and Wildlife Service (Service/FWS). If the effects are determined to be insignificant, discountable, or entirely beneficial, the lead Federal agency should make a determination that the project is not likely to adversely affect listed species or their critical habitats and request concurrence from the Service on its determination. If the effects are not insignificant, discountable, or entirely beneficial or are likely to be adverse, the lead Federal agency should initiate formal consultation with the Service. The Service then formulates its Biological Opinion (BO) on the proposed action.

> Section 7(b)(3)(A) "*. . . the Secretary shall provide to the Federal agency and the applicant, if any, a written statement setting forth the Secretary's opinion, and a summary of the information on which the opinion is based, detailing how the agency action affects the species or its critical habitat.*" 16 U.S.C. §1536(b)(3)(A)

The BO reflects the Service's analysis as to whether the effects of the proposed Federal action, when viewed against the status of the species affected, the species' environmental baseline, and cumulative effects, is likely to jeopardize the continued existence of those species. Likewise, the BO reflects the Service's formal analysis as to whether the effects of the proposed Federal action, when viewed against the status of designated critical habitat, the environmental baseline of designated critical habitat, and cumulative effects, is likely to destroy or adversely modify designated critical habitat.

II. BACKGROUND

Rozol® Prairie Dog Bait (Rozol) is a product registered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) of 1947, as amended (7 U.S.C. §136 et seq.). Under the FIFRA, use of a pesticide may be restricted by how it is registered and by its use label. A pesticide use label provides pesticide applicators with directions that consist of legal requirements that may specify when, how, and where a pesticide is applied. Pesticides that are federally registered by

the EPA as restricted-use are limited to use by pesticide applicators that are certified, often by passing a written exam, in accordance with national standards. Section 24(c) of FIFRA allows States to register an additional use of a federally registered pesticide product, or a new end use product to meet special local needs.

Rozol is an anticoagulant (hinders the clotting of blood) containing the active ingredient chlorophacinone. Rozol was registered in May 2009 (EPA Registration No. 7173-286) under Section 3 of FIFRA for use on black-tailed prairie dogs (BTPDs) (*Cynomys ludovicianus*) in 10 States: Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming. The EPA regulates pesticide use via administration of the FIFRA, and registration of pesticides by the EPA is subject to compliance with Section 7 of the ESA. In a letter dated September 30, 2010, the EPA requested initiation of ESA Section 7(a)(2) formal consultation under 50 CFR Part 402.46, Optional Formal Consultation Procedures for the FIFRA. To intiate formal consultation, the EPA posted the following information online:

Nation-wide Effects Determination for Chlorophacinone Relative to the Use of Rozol Prairie Dog Bait (EPA Reg. No. 7173-286)

- Transmittal Letter (PDF) from Arthur-Jean B. Williams, Associate Director, Environmental Fate and Effects Division to Gary Frazer, Assistant Director for Endangered Species, U.S. Fish and Wildlife Service (9/30/10) (2 pp, 51K)
- Effects Memorandum (PDF) from Jean Holmes, Acting Branch Chief, Environmental Fate and Effects Division (et.al) to Arthur-Jean B. Williams, Associate Director, Environmental Fate and Effects Division (9/29/10) (4 pp, 69K)
- Chlorophacinone Analysis (PDF) Nation-wide Effects Determination for Chlorophacinone Relative to the Use of Rozol Prairie Dog Bait (EPA Registration No. 7173-286) (9/29/10) (122 pp, 1507K)
  - Attachment I: Status and Life History for the Threatened and Endangered Species for which a May Affect Determination was made (PDF) (134 pp, 908K)
  - Appendix A: Maps Showing the Overlap of the Initial Area of Concern and the Species Habitat and Occurrence Sections (PDF) (23 pp, 10703K)
  - Appendix B: Risk Quotient (RQ) Method and Levels of Concern (LOCs) (PDF) (2 pp, 22K)
  - Appendix C: Estimation of Upper-bound Aquatic Exposure (PDF) (2 pp, 19K)
  - Appendix D: Literature Submitted During the Comment Period for "Receipt of Petition Requesting EPA to Suspend the Registration of Rozol Prairie Dog Bait and Cancel Certain Application Sites" (EPQ-HQ-OPP-2009-0684-0001) (PDF) (1 pg, 11K)
  - Appendix E: Summary of Ecotoxicity Data (PDF) (7 pp, 83K)
  - Appendix F: Bibliography of ECOTOX Open Literature (PDF) (26 pp, 227K)
  - Appendix G: Accepted ECOTOX Data Table (sorted by effect) and Bibliography (PDF) (5 pp, 89K)
  - Appendix H: The HED Chapter of the Reregistration Eligibility Decision Document (RED) for Rodenticide Cluster (PDF) (38 pp, 147K)
  - Appendix I: Summary of Chlorophacinone Incidents (PDF) (2 pp, 45K)
  - Appendix J: Calculation of Avian RQs using LD_{50} data (PDF) (1 pg, 10K)

The "Chlorophacinone Analysis" above is the EPA's Biological Assessment (BA) for the proposed action and is titled "*Risks of Chlorophacinone Use on Black Tailed Prairie Dogs to Federally Endangered and Threatened Species*" (EPA 2010b). The BA includes adverse effects determinations to 21 federally listed species and 7 critical habitats, and does not address critical habitat for the California condor (*Gymnogyps californianus*) (in California) and gray wolf (*Canis lupus*) (in Michigan and Minnesota) as those critical habitats were determined by the EPA to not overlap with the BTPD range. The BA also excluded critical habitat for the Chiricahua leopard frog (*Lithobates [Rana] chiricahuensis*) which had not yet been proposed at the time the EPA initiated consultation with the Service; however, designated critical habitat for the Chiricahua leopard frog is addressed herein. As noted in a September 9, 2011, letter to the EPA, the Service reviewed the ranges of the California condor, the Sonora tiger salamander (*Ambystoma tigrinum stebbinsi*), the Salt Creek tiger beetle (*Cicindela nevadica lincolniana*), and the Salt Creek tiger

beetle critical habitat and found no overlap with the current range of the proposed use of Rozol on BTPDs. Therefore, these species/critical habitat are not analyzed further because we do not believe those species or critical habitats are affected. The table below lists the 18 species and 7 (of 8) designated critical habitats that are analyzed in this consultation in accordance with Section 7 of the ESA.

Table 1. Federally listed species and critical habitats analyzed within this BO.

	COMMON NAME	SCIENTIFIC NAME	FEDERAL STATUS	Critical Habitat Designated/Analyzed?
1.	American Burying Beetle	*Nicrophorus americanus*	Endangered	Not designated
2.	Black-capped Vireo	*Vireo atricapilla*	Endangered	Not designated
3.	Black-footed ferret	*Mustela nigripes*	Endangered, Nonessential Experimental (Portions of AZ, CO, MT, SD, UT, and WY)	Not designated
4.	Canada Lynx	*Lynx canadensis*	Threatened, Candidate (NM)	Designated/Analyzed
5.	Chiricahua Leopard Frog	*Lithobates [Rana] chiricahuensis*	Threatened	Designated/Analyzed
6.	Eskimo Curlew	*Numenius borealis*	Endangered	Not designated
7.	Golden-cheeked Warbler	*Dendroica chrysoparia*	Endangered	Not designated
8.	Gray Wolf	*Canis lupus*	Endangered, Nonessential Experimental (WY, AZ, NM)	Designated/Not Analyzed*
9.	Grizzly Bear	*Ursus arctos horribilis*	Threatened	Not designated
10.	Gulf Coast Jaguarundi	*Herpailurus (=Felis) yagouaroundi cacomitli*	Endangered	Not designated
11.	Jaguar	*Panthera onca*	Endangered	Not designated
12.	Mexican Spotted Owl	*Strix occidentalis lucida*	Threatened	Designated/Analyzed
13.	New Mexican ridge-nosed rattlesnake	*Crotalus willardi obscurus*	Threatened	Designated/Analyzed
14.	Northern Aplomado falcon	*Falco femoralis septentrionalis*	Endangered, Nonessential Experimental (NM)	Not designated
15.	Ocelot	*Lepardus pardalis*	Endangered	Not designated
16.	Piping plover	*Charadrius melodus*	Threatened	Designated/Analyzed
17.	Preble's meadow jumping mouse	*Zapus hudsonius preblei*	Threatened	Designated/Analyzed
18.	Whooping crane	*Grus americana*	Endangered	Designated/Analyzed

*Designated critical habitat for the gray wolf exists in Michigan and Minnesota; however, the EPA determined that it does not overlap with the range of the BTPD and will not be affected by the proposed action.

III. CONSULTATION HISTORY

Prior to initiation of Section 7 consultation on the registration of Rozol in 10 States by the EPA, there was an extensive history regarding the use of Rozol for BTPD (*Cynomys ludovicianus*) control. The background information provided below includes activities/actions that occurred leading up to the current consultation and issuance of this BO. The list of consultation history items below is not intended to be all inclusive, but represents the Service's perspective of milestones in the 20-year consultation history in the use of chlorophacinone, the active ingredient in Rozol, as a rodent-control chemical. Many events involved several agencies, groups, and individuals and are relevant to understanding the issues associated with Rozol use on BTPDs.

DATE	ACTIVITY
February 26, 1991	EPA requests formal consultation with the Service on chlorophacinone for use as a rodent control agent in specific geographic areas and specific rodent species in the U.S. (EPA 1991). This chemical was part of a larger suite of chemicals for which the EPA initiated formal consultation with the Service.
March, 1993	Service issues a BO that determined the proposed use of chlorophacinone for specific rodent control activities would jeopardize the continued existence of 21 listed species (FWS 1993). BO included Reasonable & Prudent Alternatives (RPAs) to avoid jeopardy along with Reasonable & Prudent Measures (RPMs) to avoid and minimize impacts to listed species from the proposed uses of chlorophacinone. Chlorophacinone or Rozol use on BTPDs was not a described use at that time and therefore not analyzed in the 1993 BO.
October 20, 1993	EPA Region VII Office issues a letter to Kansas authorizing use of Rozol Pocket Gopher Bait for control of prairie dogs (EPA 1993).
1990s	Rozol Pocket Gopher Bait made with chlorophacinone is used on prairie dogs and begins to generate interest as a prairie dog rodenticide (Lee et al. 2005).
2000s	Six States develop Special Local Needs (SLN) labels to use Rozol on BTPDs (EPA 2010a). Service provides multiple letters to State Agricultural Departments discouraging use of Rozol on BTPDs because of secondary poisoning and impacts to non-target animals including listed species (FWS 2006a, 2006b, 2006c, 2006d).
May 5, 2006	Service provides a letter to the EPA on a pending proposal for a SLN label that would allow Rozol use in Nebraska on BTPDs (FWS 2006e). Service informs the EPA of expected secondary poisoning to non-target animals, including then-listed bald eagles, and requests that the EPA initiate Section 7 consultation under the ESA.
October 1, 2006	Nebraska SLN label allows Rozol use on BTPDs to begin October 1 (Liphatech 2006).
November 8, 2006	Rozol is applied to a BTPD town near McCook, Nebraska (FWS 2007a).
December 6, 2006	A bald eagle, then-listed as threatened under the ESA, is recovered near McCook, Nebraska, and determined to have died from chlorophacinone poisoning associated with a Rozol application on a BTPD colony (FWS

DATE	ACTIVITY
	2007a).
January 19, 2007	EPA, the Service, and other interested parties meet in Topeka, Kansas, to discuss issues related to Rozol use on BTPDs, including how to prevent impacts to black-footed ferrets (EPA 2007).
December 12, 2007	EPA, the National Marine Fisheries Service, and the Service agree that the Federal action for the FIFRA registration activities will be defined as the "authorization for use or uses described in labeling of a pesticide product containing a particular pesticide ingredient."
May 19, 2008	EPA and the Service have a multi-region conference call to discuss secondary poisoning of non-target animals from Rozol use on BTPDs (EPA 2008).
May 13, 2009	EPA registers Rozol under Section 3 of FIFRA for use on BTPDs in 10 States with an application date of October 1CMarch 15 (EPA 2009a).
June 5, 2009	World Wildlife Fund (WWF) provides a letter to the EPA that includes a request that ESA Section 7 consultation be completed for the FIFRA registration for Rozol use on BTPDs (WWF 2009). EPA treats this letter as a petition to consider suspension of Rozol as a BTPD rodenticide (EPA 2009b).
July 10, 2009	Defenders of Wildlife (DOW) and Audubon of Kansas (AOK) file a petition in the District of Columbia for judicial review of the EPA's May 13, 2009, decision to register Rozol for BTPDs, noting the lack of ESA Section 7 consultation (DOW and AOK 2009a).
July 15, 2009	DOW submits a Notice of Intent to sue the EPA for use of Rozol on BTPDs without ESA Section 7 consultation and other issues (DOW 2009).
July 30, 2009	Western Association of Fish and Wildlife Agencies (WAFWA) provides a letter to the Department of the Interior (DOI) Secretary Salazar regarding Rozol use on BTPDs requesting that DOI press the EPA to rescind use of Rozol until consultation is finished and secondary poisoning of non-target species is addressed (WAFWA 2009).
September 8, 2009	Service provides a letter to the EPA on the FIFRA Section 3 registration for Rozol use on BTPDs and requests that ESA Section 7 consultation be completed prior to use of Rozol on BTPDs and that Rozol use for that purpose be withdrawn until completion of the Section 7 consultation (FWS 2009a).
September, 2009	Black-footed ferret reintroduction site information is provided to the EPA in response to the EPA's request for areas where Rozol use might conflict with black-footed ferrets.
September 23, 2009	DOW and AOK file a complaint in the U.S. District Court of Columbia (USDC) alleging among other things that the EPA failed to conduct ESA Section 7 consultation for the use of Rozol on BTPDs (DOW and AOK 2009b).
September 30, 2010	EPA submits a letter to the Service requesting formal ESA Section 7 consultation on Rozol use on BTPDs (EPA 2010b).
November 16, 2010	EPA rejects suspension of Rozol as a BTPD rodenticide in response to

DATE	ACTIVITY
	the WWF's letter of June 5, 2009, which had been considered a petition by the EPA (EPA 2010c).
June 14, 2011	USDC issues a ruling on the DOW and AOK litigation against the EPA (USDC 2011). The Court ruled against the groups on some points but found that ESA Section 7 consultation must be completed. A date was set to hear arguments whether to suspend use of Rozol until Section 7 is completed.
July 13, 2011	Service provides a signed declaration to the court indicating that a draft BO will be provided to the EPA by December 10, 2011 (FWS 2011a).
August 8, 2011	In response to the litigation outcome, the EPA issues a cancellation order and modifies the Rozol label to indicate that Rozol is not a labeled use in MT, ND, NM, or SD (EPA 2011a). Upon completion of the BO, the EPA anticipates a label modification to add those States back onto the label.
August 26, 2011	A bald eagle picked up in Nebraska in the spring of 2011 is confirmed to have died of chlorophacinone poisoning (FWS 2011b).
September, 2011	EPA and the Service discuss conservation measures that could be developed and instituted to avoid and minimize adverse effects to listed species, agreeing to include the registrant and applicant, Liphatech, Inc., (Liphatech) in those discussions.
September 28, 2011	A conference call is held between Liphatech, the EPA, and the Service that included discussion on general aspects of formal Section 7 consultation and the development of conservation measures that would avoid and minimize impacts to listed species from Rozol use on BTPDs. All parties were receptive to development of conservation measures that could be integrated into the proposed action.
October, 2011	Due to interest in the conservation measures, the Service inquires of Liphatech and the EPA whether the draft BO deadline of December 10, 2011, can be extended to allow the conservation measures to be finalized and incorporated into the proposed action. This change in the proposed action is expected to significantly modify the anticipated impacts to listed species, and the parties agree that additional time can be afforded.
October, 2011	Service begins providing maps of listed species areas where Rozol use should be prohibited to avoid adverse affects or where the use dates of October 1 - March 15 would be restricted to avoid listed species interaction with BTPD colonies that have had Rozol applications. EPA provides this information to Liphatech.
October 17, 2011	EPA sends a response to the Service's September 9, 2011, letter that had requested additional information from the 1993 chlorophacinone BO (EPA 2011b). EPA letter indicates that no additional information is available; RPAs, RPMs, and suggested animal studies from the 1993 BO were either not implemented or information is not available on the implementation.
November 8, 2011	EPA and the Service discuss, via conference call, possible conservation measures and confirm the information to be provided to Liphatech.

DATE	ACTIVITY
November 22, 2011	Service provides a signed declaration to the court indicating that the Service will provide a draft BO to the EPA by January 16, 2012, per the understanding with the EPA that additional time for drafting the BO is warranted for development of the conservation measures (FWS 2011d).
December 13, 2011	EPA provides a letter to the Service and Liphatech that formalizes the agreed upon conservation measures to avoid and minimize impacts to listed species (EPA 2011c). This letter modifies the proposed action and the subsequent analysis in the BO is changed to reflect the new information.
January 16, 2012	Service provides a draft BO to the EPA.
January 18, 2012	EPA posts the draft BO on their website for public comment.
March 9, 2012	EPA provides comments to the Service on the draft BO (EPA 2012a).
April 6, 2012	Additional Conservation Measures are agreed upon that will incorporate improved post application survey language and contact information on the Rozol label, development of a website and training materials intended to reduce nontarget exposure, and conduct training sessions for applicators in the proper use of Rozol and the importance of preventing exposure to nontarget animals (EPA 2012b).
April 9, 2012	Final BO for Rozol use on BTPDs registered under Section 3 of the FIFRA provided to EPA.

IV. DESCRIPTION OF THE ACTION

The proposed action by the EPA is the administration of the FIFRA Section 3 registration of the single product label for Rozol (Registration No. 7173-286). Rozol is manufactured by Liphatech as loose-grain bait used to poison BTPDs in the 10 western States of Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming. Its use in the States of Montana, New Mexico, North Dakota, and South Dakota was cancelled in August 2011, pending completion of the ESA Section 7 consultation; however, the EPA and Liphatech propose to resume application in those States upon completion of this Section 7 consultation.

All 10 States listed on the September 10, 2010, Rozol label (see Appendix) are considered herein. The EPA's goal for reassessing registered pesticide active ingredients is every 15 years. Given the EPA's timeframe for pesticide registration reviews, the Service's evaluation of the proposed action is also for 15 years.

The EPA adopted conservation measures during the formal consultation process and incorporated them as part of the proposed action (EPA 2011c, 2012b); those measures are listed below. The action area and items relevant to use of the product, as directed by its label, were described in the EPA formal consultation initiation package (EPA 2010b) and incorporated herein. Additionally, information regarding direct and indirect effects of the proposed action and potential exposure routes to federally listed species, as well as a review of the EPA's BA, is provided in this BO. This information provides the context in which the subsequent individual species analyses were conducted.

A. CONSERVATION MEASURES

Conservation measures are commitments by the EPA to avoid or minimize adverse impacts of the proposed action and, for the purposes of this consultation, are considered part of the proposed action that are then analyzed in the effects analysis in this BO. The Service identified these conservation measures and coordinated with the EPA and Liphatech regarding the acceptability of the measures as well as the best means to implement them. The measures 1-8 below were formally adopted by the EPA via letter dated December 13, 2011, and will be included online as part of the EPA's Endangered Species Protection Bulletins (see: *Bulletins Live!* at http://www.epa.gov/espp/bulletins.htm). Measures identified on the EPA's *Bulletins Live!* are considered an extension of the Rozol label thereby legally requiring applicators to adhere to them (EPA 2011c). Maps of each of the areas where Rozol use will not be allowed or restricted, along with any associated relevant information will be included in the EPA's *Bulletins Live!* database, and label requirements will make clear that Rozol use in these areas is restricted or prohibited. On April 6, 2012, additional conservation measures were agreed upon and incorporated into the project proposal and described below (EPA 2012b). Noncompliance with these bulletins would be a violation of FIFRA.

1. **Black-footed Ferret Conservation Measure**
   - Prohibit application of Rozol within current black-footed ferret reintroduction sites (13 sites) and future reintroduction areas to reduce the level of impact to the black-footed ferret. The locations will be made available via the EPA's *Bulletins Live!* database.

2. **Chiricahua Leopard Frog Conservation Measure**
   - Prohibit application of Rozol within the five southwestern New Mexico counties of Catron, Grant, Hidalgo, Sierra, and Socorro to avoid impacts to the Chiricahua leopard frog and its critical habitat.

3. **Grizzly Bear Conservation Measure**
   - Delay application of Rozol in the State of Montana by 2 months until December 1, and shorten the application period in the spring by 2 weeks to end by March 1, in areas where the range of the grizzly bear overlaps with the range of the BTPD to reduce the risk of impacts to the grizzly bear.

   - The areas in Montana where the timing delay applies includes all, or portions of, the following counties: Carbon County; Stillwater County south of I-90; Sweetgrass County south of I-90; Park County south of I-90; Gallatin County south of I-90; Madison County; Powell County; Lewis and Clark County; Cascade County; Teton County; Pondera County; Glacier County; and Toole County.

4. **Jaguar Conservation Measure**
   - Prohibit application of Rozol within the southwestern New Mexico County of Hidalgo to reduce the risk of impacts to the jaguar.

5. **New Mexico Ridge-nosed Rattlesnake Conservation Measure**
   - Prohibit application of Rozol within the southwestern New Mexico county of Hidalgo to avoid impacts to the New Mexico ridge-nosed rattlesnake and its designated critical habitat.

6. **Mexican Gray Wolf Conservation Measure**
   - Prohibit application of Rozol within the four southwestern New Mexico counties of Catron, Grant, Hidalgo, and Sierra to reduce the risk of impacts to the Mexican gray wolf within the Blue Range Wolf Recovery Area.

7. **Mexican Spotted Owl Conservation Measure**
   - Prohibit application of Rozol within the five southwestern New Mexico Counties of Catron, Grant, Hidalgo, Sierra, and Socorro to reduce the risk of impacts to the Mexican spotted owl and its designated critical habitat.

8. **Preble's Meadow Jumping Mouse Conservation Measure**
   - Delay application of Rozol in the fall by 1 month, until November 1, in areas where the range of the Preble's meadow jumping mouse (PMJM) overlaps with the range of the BTPD to reduce the risk of impacts to the PMJM.

   - Areas where the timing delay applies exist within Wyoming and Colorado. Within Wyoming, all or portions of the following four counties are to have the above timing restriction: Converse, Platte, Albany and Laramie. Within Colorado, the timing restriction applies within the following seven counties: Larimer, Boulder, Weld, Jefferson, Douglas, Elbert, and El Paso.

As previously noted, on April 6, 2012, additional conservation measures were added and the suggested label language below will be included, with the exception of the following statement: "*Detailed guidance on how to conduct a line-transect search is available online at (*EPA website*)*", which EPA will add once content is developed in coordination with FWS and Liphatech (EPA 2012).

> *"Carcass searches must be performed using a line-transect method that completely covers the baited area. Detailed guidance on how to conduct a line-transect search is available online at (EPA website). Transect center lines must be no more than 200 feet (about 60 meters) apart, and should be considerably less if searches are conducted in more densely vegetated sites. Transect lines may be traveled on foot or by vehicle at a rate not to exceed 4 mph. All dead or dying non-target animals must be reported to the National Pesticide Information Center 1-800-858-7378 as soon as possible. Any apparently injured or sick Federally listed species must also be immediately reported by calling 303 –236 - 7540 (if located in Kansas, Nebraska, the Dakotas, Montana, Colorado, or Wyoming) or 505 –248-7889 (if located in Texas, New Mexico or Oklahoma). The Black-footed Ferret Coordinator must also be contacted if ferrets are found during Rozol Prairie Dog Bait applications or carcass searches at 970-897-2730 x 224."*

The EPA believes that improved Rozol Prairie Dog Bait label language in combination with education and outreach activities are appropriate. Therefore, EPA, with agreement from Liphatech, includes the following Conservation Measures:

1. Liphatech will add language to the Rozol Prairie Dog Bait label as agreed to on the March 30, 2012 conference call. The Rozol Prairie Dog Bait label will also explicitly state that pesticide applicators are responsible for ensuring that carcass searches are performed in accordance with the label requirements.

2. EPA, in coordination with FWS and Liphatech, will develop website content intended to achieve the following:
   a. Provide information on the importance of limiting the availability of dead and dying target and non-target wildlife in order to protect the listed species of concern;
   b. Describe the improved carcass search methods described in this Conservation Measure; and
   c. Include the website link as part of the Rozol Prairie Dog Bait label once it is developed.
3. EPA will work with the State Lead Agencies to incorporate training sessions on secondary poisoning at their annual pesticide applicator recertification programs. The training will educate applicators on the meaning of secondary toxicity, the hazards of Rozol Prairie Dog Bait, the basis for the carcass search requirements and other associated label restrictions and the importance of minimizing risk to non-target species. EPA staff may participate directly in these training sessions, through webinars, by helping to arrange for other knowledgeable persons to give presentations, or through a combination of each.

4. As a condition of registration Liphatech will maintain a stewardship program using the framework as described below:

LIPHATECH ROZOL PRAIRIE DOG BAIT PRODUCT STEWARDSHIP PROGRAM

PURPOSE

The Liphatech Rozol Prairie Dog Bait Product Stewardship Program is a commitment by Liphatech to provide education and outreach materials and training to Rozol Prairie Dog Bait users (e.g., certified applicators and landowners) on carcass search and survey methods described on the Rozol Prairie Dog Bait label. The purpose of this program is to result in minimized take to the affected listed species of concern via reduction in the incidence of secondary poisoning.

REQUIREMENTS

a. On its Rozol Prairie Dog Bait product website, Liphatech will include a link to EPA's Rozol Prairie Dog Bait bulletins, which provide geographically-based prohibitions on Rozol Prairie Dog Bait use intended to protect listed species of concern.

b. Liphatech will provide yearly training sessions to pesticide applicators in each of the 10 States where Rozol Prairie Dog Bait will be registered. To the extent possible, Liphatech will provide these training sessions prior to the 2012 Rozol Prairie Dog Bait

use season. The training sessions will include information on proper dosing for Rozol Prairie Dog Bait, presentation of the carcass search and line transect survey methods listed on the Rozol Prairie Dog Bait label, and education on the meaning of secondary toxicity and the importance of minimizing secondary exposure to non-target species.

c. Once EPA, FWS, and Liphatech have developed website content, Liphatech will include a link to EPA's website on its Rozol Prairie Dog Bait product website. In addition, Liphatech will develop and distribute a brochure with information from the website to be distributed as part of its training sessions and other outreach initiatives.

B. ROZOL PRAIRIE DOG BAIT REGISTERED USE

The chlorophacinone concentration in Rozol is 0.005 percent or 50 milligrams per kilogram (mg/kg). According to Rozol label instructions (Appendix), the product is to be applied by certified applicators to BTPD colonies in rangelands and noncrop areas by inserting ¼ cup (53 grams, nearly 2 ounces) by hand at least 6 inches into active prairie dog burrows only between October 1 and March 15 of the following year, when the prairie dogs most readily consume grain bait. Any bait spilled above ground or placed less than 6 inches into the burrow is to be retrieved and disposed of by the applicator. Prairie dogs that consume the bait are anticipated to begin dying within 4-5 days. The label indicates that the applicator must return to the site within 4 days after bait application and at 1- to 2-day intervals thereafter for at least 2 weeks (longer if carcasses continue to be found) to collect and properly dispose of any bait or dead or dying prairie dogs found at the surface. These return visits to collect bait and prairie dogs are to occur late in the day, near sundown, to reduce the potential of nocturnal animals finding dead and dying animals. Carcasses may be buried onsite, at least 18 inches below the surface, or placed in inactive burrows, and burial must include covering and packing the soil atop the carcass. If onsite burial is not possible, other means of disposal to preclude scavenger access to carcasses is required. A second application may be made if prairie dog activity persists several weeks or months after the initial bait application.

C. ACTION AREA

The action area is defined (50 CFR § 402.02) as all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action. The EPA has identified the action area as follows:

> *"For this assessment, BTPD range within the states of Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas and Wyoming and counties adjacent to this range is considered to be the action area. The action area considered for direct effects includes the BTPD range within the 10 states listed above as well as counties adjacent to this range. The action area considered for indirect effects includes only the BTPD range with the 10 states listed above and does not include counties adjacent to this range. This distinction was made because indirect effects are not expected to extend beyond the use area. However, direct effects may extend beyond the use area due to exposure to individuals or via prey items with chlorophacinone residues that could be found outside of their described range.*

It is important to note that the historic range-wide action areas do not imply that direct and/or indirect effects and/or critical habitat modification are expected or are likely to occur over the full extent of the action area, but rather to identify all areas that may potentially be affected by the action. The Agency uses more rigorous analysis including consideration of available land cover data, toxicity data, and exposure information to determine areas where listed species and their designated critical habitats may be affected or modified via endpoints associated with reduced survival, growth, or reproduction."

In the BA, the EPA provided a map of the historic BTPD range from NatureServe (Figure 2.2 on page 55 of the BA, reproduced below in Figure 1) as an indicator of the action area and described as the "footprint" or "initial area of concern" which covers all habitats within the historic BTPD range. Range maps available on the Service's website (http://www.fws.gov/endangered) for federally listed species and/or their critical habitats were overlaid by the EPA on that historic BTPD map to determine any overlap which was used in the EPA's BA to inform "May Affect" determinations for federally threatened or endangered species and their critical habitats. As the EPA recognized in the BA, the historic range map of the BTPD does not necessarily include the entire "Effects Determination Area" and additional data were used as appropriate to determine effects to species and critical habitats. The current range of the BTPD has contracted from its historic range so, in some areas, the species' current overlap with federally listed species has been reduced (FWS 2009b). The consultation addresses Rozol use within the 10 States identified on the September 10, 2010, Rozol label (Appendix). Additionally, some of the conservation measures listed above further amend the EPA's action area by precluding Rozol use in some areas. For the purposes of this consultation, and in accordance with the definition of "action area" provided above, the Service agrees with the EPA's broad action area. The EPA's demarcation of areas where direct effects versus indirect effects may occur is not adopted herein, as we surmise that indirect effects could occur in counties adjacent to the BTPD's range. However, we agree with the EPA's clarification that, while the action area includes those areas adjacent to the BTPD's range where potential affects may occur, those affects are not necessarily likely or expected to occur and additional information was used to determine affects to listed species.

Figure 1. The historic range of the BTPD by NatureServe as presented in the EPA's BA (EPA 2010b).

V. GENERAL BACKGROUND AND EFFECTS OF THE ACTION RELEVANT TO ALL SPECIES IN CONSULTATION

The BTPDs are considered a keystone species that have a unique and substantial influence on plant and animal communities and are critical to the integrity of grassland ecosystems (Kotliar et al. 2006). The habitat they create is associated with more than 150 species of amphibians, birds, mammals, plants, and reptiles as well as species federally listed for protection under the ESA (Kotliar et al. 2006). In western South Dakota, 40 percent of all wildlife (represented by 134 vertebrate species) is associated with BTPD colonies (Sharps and Uresk 1990). The presence of mountain plovers (*Charadrius montanus*) and burrowing owls (*Athene cunicularia*), two species of conservation concern (FWS 2008a), is also considerably higher on BTPD colonies than grassland habitats without prairie dogs in eastern Colorado (Tipton et al. 2008). When prairie dog towns are poisoned, many other species are likely to be poisoned as well or be negatively affected by loss of prairie dog habitat or the species associated with that habitat. Loss of seasonal habitat for bird species may be of special concern. The number of bird species present in the summer was significantly higher on prairie dog towns than paired sites without prairie dog towns (Smith and Lomolino 2004). Burrowing owls, killdeer (*Charadrius vociferous*), horned larks (*Eremophila alpestris*), and western meadowlarks (*Sturnella neglecta*) are positively and significantly associated with prairie dog towns during summer, while horned larks and ferruginous hawks (*Buteo regalis*) are significantly associated with prairie dog towns during fall (Smith and Lomolino 2004). Species' declines from the reduction of prairie dog habitat can result in cascading effects through the grassland ecosystem that extend beyond the poisoned prairie dog towns.

A. INDANDIONE MODE OF ACTION AND TOXICITY

Chlorophacinone, the active ingredient in Rozol, is an anticoagulant chemical and, along with diphacinone, belongs to the indandione class of compounds. Chlorophacinone and diphacinone are the only indandione active ingredient rodenticides currently registered for use in the United States. Diphacinone was registered to poison BTPDs under FIFRA Section 24(c) for SLN, but it is currently registered for use only on rodents other than prairie dogs. Rozol is the only anticoagulant registered for use on BTPDs that is registered under Section 3 of FIFRA. Indandiones depress liver synthesis of vitamin K-dependent blood-clotting factors and increase permeability of capillaries throughout the body, resulting in systemic internal hemorrhaging (Reigart and Roberts 1999). Unlike the coumarin class of anticoagulant compounds (e.g., warfarin, brodifacoum, difenacoum), indandiones can cause neurologic and cardiopulmonary injury leading to death before hemorrhage occurs (Reigart and Roberts 1999, Hazardous Substances Data Bank 2003). Indandiones also uncouple oxidative phosphorylation (energy generation) which may result in fatigue and restlessness (Van Den Berg and Nauta 1975, Bryson 1996). Clinical effects typically do not occur until several days after ingestion due to the persistence of blood-clotting factors. In humans, clinical effects include anemia (red blood cell deficiency), fatigue, dyspnea (breathlessness), nosebleeds, bleeding gums, hematuria (blood in the urine), melena (darkened feces associated with gastrointestinal bleeding), and extensive ecchymosis (large bruises) (Reigart and Roberts 1999).

Indandiones are first generation anticoagulant rodenticides that are most toxic when animals are exposed to daily doses for multiple days (Vyas and Rattner 2012). For example, the median Lethal Dose (LD_{50}) from a single exposure of chlorophacinone to Norway rats (*Rattus norvegicus*) is 20.5 micrograms per gram (µg/g), whereas a 5-day daily dose LD_{50} is 20 times lower at 0.95 µg/g (Jackson and Ashton 1992). A risk assessment by the EPA (Erickson and Urban 2004) reports a laboratory rat chlorophacinone LD_{50} of 6.2 µg/g as well as a 0.19 µg/g 5-day LD_{50} for the same species (Table 9, page 34) indicating a 6-fold difference that is also probably attributed to differences in exposure frequency and duration. Likewise, a dietary toxicity test that provided a measured diphacinone-treated diet for daily consumption by eastern screech-owls (*Megascops asio*) found that repeated low-dosage exposure over 7 days increased diphacinone toxicity by more than an order of magnitude compared to an acute oral toxicity test (Rattner et al. 2011a; Vyas, pers. comm. 2011a; Vyas and Rattner 2012). Thus, the single dose LD_{50} test, which was developed to evaluate rodenticides causing acute responses such as zinc phosphide, is not an appropriate test for evaluating toxicity for first generation anticoagulants such as chlorophacinone that have their greatest toxicity from repeated daily exposures. We believe that acute standardized toxicity test results for chlorophacinone greatly underestimates risk to non-target species because indandiones are much more lethal when multiple doses are consumed over multiple days as opposed to a single feeding.

The BTPDs exposed to chlorophacinone exhibit much variability in their susceptibility to mortality and the amount of time it takes for them to die (Yoder 2008). Death can occur when exposed to a chlorophacinone dose (oral gavage) as low as 0.5 milligrams per kilogram body weight (Yoder 2008). Mortality from LD_{50} tests indicate that BTPD deaths tend to occur 9-20 days after exposure (Yoder 2008). The BTPDs exposed to chlorophacinone may not exhibit any symptoms prior to death, but most are symptomatic for at least 24 hours before death (Yoder 2008). The BTPD symptoms from chlorophacinone exposure (e.g., loss of attentiveness, lethargy, swollen or closed eyes) generally take days after ingestion to manifest, and this likely reduces bait avoidance in the interim (Yoder 2008). There is no apparent taste aversion to Rozol as BTPDs readily consume Rozol bait (Witmer 2011).

B. CHLOROPHACINONE ENVIRONMENTAL FATE

The number of days for chlorophacinone to degrade by 50 percent (half-life) has been reported by laboratory studies that evaluate degradation by soil, water, and light. The half-life of chlorophacinone incorporated in soil can range from 4 to 128 days depending on laboratory testing conditions. In soil under dark aerobic conditions at 25°C, chlorophacinone is degraded steadily with an estimated half-life of 128 days (European Commission 2009); whereas, under artificial light on sandy clay loam soil, chlorophacinone's half-life is 4 days (EPA 1998a). Although previously reported to be very susceptible to direct photolysis in water (e.g., half-life of 37 minutes at pH 7), the assessments used acetone (a strong photosensitizer) as a solvent to introduce chlorophacinone into the test system and are now considered by the EPA as invalid (Jones, pers. comm., 2011). Chlorophacinone is stable in water at a pH of 5, 7, or 9; thus, breakdown by exposure to water is not expected to be an important degradation process (Hazardous Substances Data Bank 2003).

Few studies have evaluated the field persistence of chlorophacinone rodenticide baits; however, they indicate that chlorophacinone concentrations in Rozol would not degrade prior to consumption even under wet conditions (Merson and Byers 1985; Jones, pers. comm., 2011). A field study that evaluated wet weather resistance of rodenticides, including Rozol Vole Bait, found no difference in efficacy between wet and dry chlorophacinone pellets (Merson and Byers 1985). A supplemental terrestrial field dissipation study reported no dissipation of chlorophacinone in Rozol samples for up to 10 days and actually found concentrations increased over this time period, perhaps as a result of insect consumption of the internal part of the grain or changes to bait water content (Jones, pers. comm., 2011). The ability to evaluate dissipation of chlorophacinone on grain samples was hampered by consumption of the grain samples, and the study concluded that the primary route of dissipation of chlorophacinone is through consumption of the treated grain (Jones, pers. comm., 2011).

Based on the information above, we agree with the EPA's assumption in the BA (EPA 2010b) that the mobility from bait into soil or water is considered a negligible exposure pathway to non-target organisms. We assume chlorophacinone remains undegraded in bait after applications and share the EPA's assumption that the only relevant dissipation of Rozol occurs through its consumption.

C. ROZOL EXPOSURE AND EFFECTS ASSESSMENT

1. Primary Exposure

Ingestion of Rozol (primary exposure) by non-target species can be expected for species that feed on grain. Twenty-nine adult domestic pigeons (*Columba livia*) were poisoned in Spain with a 0.005 percent chlorophacinone wheat grain bait after a broadcast application targeted at common voles (*Microtus arvalis*) (Sarabia et al. 2008). A common lesion associated with chlorophacinone toxicosis in these pigeons involved massive hemorrhage and hematoma formation in the subcutis of the neck; however, equally noteworthy was that chlorophacinone was found in the liver at 5.66 to 34.97 µg/g wet weight (ww) basis in four birds without any lesions suggestive of anticoagulant toxicosis (Sarabia et al. 2008). Although the label requirement to place bait "six inches in the burrow" is designed to limit exposure to granivorous birds, it does not preclude exposure to avian or other non-target species that may use BTPD holes. Rozol was visible in many BTPD burrows that contained angled entrances (as opposed to vertical entrances), and horned larks appeared to be preferentially drawn to these burrows where they could easily feed on Rozol (Vyas 2010a). The presence of green-stained droppings, indicative of exposure to Rozol bait which contains a green dye thereby making product appear green, was observed and suspected to be from pheasants (*Phasianus colchicus*), horned larks, and western meadowlarks. Green droppings from these birds suggest they were consuming bait; an assumption subsequently confirmed by detection of chlorophacinone residues in these droppings (Vyas, pers. comm., 2011b).

In addition to feeding on bait within the burrow, non-target species may also feed on bait found on the surface. Bait spilled by applicators or not entirely placed in burrows can be difficult and time consuming to collect. Further, bait that is placed in burrows can be brought back to the surface of a colony over time by the action of prairie dogs and other animals using the burrow

system (Vyas 2010a). We currently lack information concerning applicator willingness to cease operations and collect misplaced bait or return to the colony days to weeks later to collect and dispose of bait found on the surface. Absent that information, it appears that bait retrieval from the surface of a prairie dog colony, days to weeks post application, could be an unrealistic expectation of the label. Thus, even if applicators attempted to follow label instructions regarding retrieval and disposal of bait at the time of application, the size of bait and landscapes where it is used brings up the practicality of adhering to that label requirement. We are aware of one field study that found bait on the surface (Vyas 2010a) and have no information from anywhere else that indicates applicators are collecting and disposing of bait found above ground.

The Rozol application rate of approximately ¼ cup of bait (53 grams) down each active prairie dog burrow may be excessive and likely results in increased risk to non-target species. According to Liphatech, 53 grams of Rozol bait provides about 2 LD_{50} doses per BTPD, based on a single dose oral gavage LD_{50} of 1.8 µg/g (Yoder 2008). However, as previously explained, a 5-day LD_{50} would likely be around 20 times lower than a single dose LD_{50} and is more representative of exposure in the field whereby animals may consume bait over multiple days. Thus, 53 grams of bait may provide 10 LDs_{50}. Furthermore, there are on average 3.9 active burrow entrances for each BTPD (Biggins et al. 2006). If inactive burrows are mistakenly baited, then even further bait availability to both target and non-target animals would occur. To illustrate the point, when Forgacs (2010) treated 1,358 burrows on a 15.7 acre prairie dog plot where they had a visual count of 30 prairie dogs, they applied 71,974 grams of Rozol (at least 13,580 LDs_{50}) on a plot with an estimated population of 348 BTPDs using a scientifically accepted methodology to estimate prairie dog numbers from active burrows (Biggins et al. 2006). While that level of dosing likely ensures high lethality to prairie dogs, it likely also contributes to prairie dogs consuming multiple LDs_{50} as well as providing left-over bait to remain available for non-target species to consume after the prairie dogs have been killed.

Results from other studies indicate that application rates of less than 53 grams of product per active burrow can be effective at killing BTPDs. Sullins (1990) reported a 96-percent reduction in the visible count of BTPDs after providing 0.01 percent chlorophacinone product in 2 applications of 9 grams per active burrow for a total of 18 grams (equivalent to 36 grams of Rozol) applied within 48 hours.

2. Secondary Exposure

Species that ingest animals that consume Rozol (secondary exposure) are also at risk of being negatively affected, especially predators and scavengers that may gorge on poisoned prairie dogs and selectively feed on internal tissues (see "Prairie Dog Chlorophacinone Residues" section below). Five of six domestic ferrets were killed after each ferret was fed four poisoned BTPDs over 8 days; the authors of the study concluded that chlorophacinone may not be an acceptable prairie dog toxicant based on high secondary toxicity (Fisher and Timm 1987). As described further in the "Field Study Observations of Secondary Toxicity" section below, field observations indicate that the availability of BTPDs to secondary consumers is facilitated by prairie dogs spending time above ground after ingesting Rozol (FWS 2007a, Golden and Gober 2010, Vyas 2010a). When subjected to poisoning, BTPDs can return to the surface of the colony, becoming increasingly debilitated until death. Prairie dogs in this debilitated state can be

more susceptible to predation due to changes in behavior that render them more conspicuous and less wary and evasive in the presence of a predator (Hunt et al. 1992, Relyea and Hoverman 2006). Avian predator hunting success increases dramatically when injured or abnormal prey are available (Rudebeck 1950), and scavengers, including some raptors, are attracted to easily obtained food sources, including poisoned prey (Chesser 1979, Vyas 1999, Vyas et al.2003). Some avian predators such as ferruginous hawks are attracted to Rozol-treated prairie dog colonies, likely due to the increased presence of moribund and dead prairie dogs and perhaps other non-target species (Vyas 2010a). Thus, even though Rozol-treated prairie dog colonies may make up only a small percentage of a predator's overall foraging range, preferential selection of prey from these areas may lead to a disproportionate opportunity for exposure.

Risk to non-target species also includes effects from chronic (long-term) secondary exposure. Rozol exposed prairie dogs may be debilitated on the surface for at least a month following application (Vyas 2010a, Lee and Hygnstrom 2007). Thus, predators may continue to feed from the same poisoned prairie dog town for weeks or may encounter other poisoned prairie dog towns that were sequentially poisoned and are within their home range or migration path. As described earlier, lethality of Rozol increases greatly with repeated exposure. We assume that many of the effects described in the above "Indandione Mode of Action and Toxicity" section including sub-lethal neurologic effects, cardiopulmonary effects, energy loss, and hemorrhaging could occur in federally listed species from chronic Rozol exposure and ultimately result in decreased growth, survival or reproductive effects. Further, we agree with the EPA's assessment in the BA that "toxicity resulting from chronic exposure exceeding five days cannot be determined based on current data" and that "growth and reproductive effects cannot be precluded due to the absence of chronic data."

The BA and previous risk assessments by the EPA (Erickson and Urban 2004) indicate that mammals are at a greater risk from secondary chlorophacinone toxicity than birds; however, if sub-lethal effects are considered, then birds exposed in the field may be at equal or greater risk than mammals as the effects of anticoagulant rodenticide toxicosis can differ between mammal and avian species. For example, pulmonary hemorrhage is far more common in mammals than birds, but birds can have excessive external bleeding from minor superficial wounds, a condition not reported in mammals (Stone et al. 1999). Also, the first observed signs of secondary chlorophacinone toxicity in raptors include fatigue such as wing-drooping (Radvanyi et al. 1988). For species such as raptors that rely upon speed and stamina to attain prey, chlorophacinone-induced fatigue can result in decreased survival by impairing their ability to capture prey. Because of differences in pathologies, birds may be even more susceptible to chronic effects than mammals. Furthermore, some avian species may be just as susceptible as mammals or more susceptible when sub-lethal effects are considered in conjunction with other factors that influence exposure and cumulative effects to birds such as: a) body condition from migration; b) increased susceptibility to contact injury; c) environmental conditions such as weather extremes; and d) high energy demands in the winter.

3. Surface Presence of Poisoned Black-tailed Prairie Dogs

The greatest pathway for effects to listed species from the proposed action comes from moribund or dead animals found on the surface of a prairie dog colony as a result of Rozol poisoning. The Service is aware of three studies that inform the issue of dead and dying prairie dogs on the colony surface following Rozol application, and two of the three studies repeatedly found dead and dying prairie dogs above ground on the surface of the prairie dog colony during multiple return visits (Lee and Hygnstrom 2007, Vyas 2010a). The other study (Forgacs 2010) did not find prairie dogs on the surface but qualified that result noting that weather conditions deteriorated after the application to the point that precipitation prevented researchers from even being able to return to some poisoned sites to search for prairie dogs. That study also noted that the inclement weather, which began after the Rozol application, may have contributed to decreased above-ground prairie dog activity (Forgacs 2010).

Instances of dead and dying prairie dogs above-ground following application have also been reported to the Service's Law Enforcement Division (FWS 2007a, Golden and Gober 2010). An excerpt below from an interview with a Rozol applicator after a bald eagle (*Haliaeetus leucocephalus*) poisoning incident in Nebraska illustrates both the regularity that prairie dogs return to the surface and the state of awareness of Rozol poisoned prairie dogs (FWS 2007a).

> REDACTED *also explained that he knew poisoned prairie dogs often returned to the surface before dying, as evidenced by the bloody stools he often saw when he returned to inspect the sites.* REDACTED *further relayed an incident when the poison Rozol had been applied to the prairie dog town, as per label instructions and the lady owning the property watched as poisoned prairie dogs stumbled around the surface for two weeks after the application.* REDACTED *added when he does see prairie dogs on the surface after they have been poison, they seem to be in a stupor, and not wary at all.* REDACTED *said he could often walk right up to these poisoned prairie dogs and they would not run away.*

At the time this statement was provided to Law Enforcement Agents in 2007, the Rozol SLN label did not require collection of impaired or moribund prairie dogs but rather just retrieval of carcasses found on the surface. Even though the current label requires collection and disposal of live prairie dogs, we have encountered applicators who indicate that this is not readily accomplished (see following section below). Given the instances of Service Law Enforcement agents finding moribund and dead prairie dogs on the surface after a Rozol application (Golden and Gober 2010) and applicators reporting prairie dogs on the colony surface following Rozol applications (FWS 2007a), we believe Rozol-poisoned prairie dogs and other animals will regularly return to the surface of a colony and be available for secondary exposure to federally listed species, including the northern aplomado falcon and gray wolf.

4. Removal of Poisoned Black-tailed Prairie Dogs

Although the Rozol label requires return visits to the colony to search for and remove dead and dying prairie dogs following application, the limited information on applicator behavior indicates that few, if any, moribund or dead prairie dogs are collected and disposed of in a manner that

substantially reduces secondary exposure (FWS 2010a, Tosh et al. 2011). This outcome may be due to the difficulty of finding prairie dogs on the surface as illustrated by Vyas (2010b) (click here for video) or because resources and commitments needed to make multiple return visits to a colony are not available (FWS 2010a).

During a meeting in 2010 attended by the EPA and hosted by the North Dakota Department of Agriculture and Standing Rock Sioux Indian Reservation, ranchers and professional pesticide applicators indicated that they do not have the time, resources or inclination to conduct multiple return visits to a Rozol treated prairie dog colony to collect dead and dying prairie dogs, and that current label requirements for two return visits to treated prairie dog towns were unrealistic and impractical (FWS 2010a). These remarks were in response to an EPA inquiry to the attendees what they would think about increasing the required returns visits to a poisoned prairie dog colony from two times as required by the label in effect at that time (August 2010) to potentially many more visits. The EPA prefaced their inquiry to the ranchers in attendance that additional return visits might be added to the label to address comments that the EPA received from environmental groups about dead and dying prairie dogs on the surface of a colony. One of the meeting participants indicated that, if the EPA needed to increase the number of return visits on the label to pacify environmental groups, it may not matter since that speaker did not believe there was rigorous adherence for two return visits to collect prairie dogs; thus, requiring even more return visits would likely meet a similar fate. The Montana Department of Agriculture also questioned the practicality of the Rozol label, especially the retrieval of live prairie dogs, and expressed their belief that most applicators will have difficulty with strict adherence to the label (de Young 2009). Of particular note from that North Dakota meeting was that none of the attendees had ever picked up and disposed of live prairie dogs or their carcasses after a Rozol application. At the time of the meeting, Rozol had only been approved for use on prairie dogs for one season in North Dakota and South Dakota. Some attendees have since indicated that applicators did go back out to search per the label and did not find BTPDs on the surface, surmising that above-ground BTPDs had been scavenged or died underground.

A recent on-farm survey on anticoagulant use in Northern Ireland found that applicators seldom followed best practice guidelines designed to maximize efficacy and reduce risk of non-target species exposure (Tosh et al. 2011). They found that applicators almost never searched for and removed poisoned carcasses and many baited for prolonged periods or permanently. We are not aware of any similar anticoagulant use behavior studies conducted in the United States that would inform Rozol applicator use behavior. However, we suspect that challenges with label restrictions, especially retrieval of live prairie dogs and carcasses, is an issue given the amount of effort needed to accomplish this task and the few resources available to ensure compliance. We conclude that while most labels are difficult to enforce, the comparatively complex nature of the Rozol label renders it particularly vulnerable to noncompliance, and reports from users indicate that failure to pick up prairie dogs is a "widespread and commonly recognized practice," a designation outlined in FIFRA as a means for determining registration eligibility.

Pamphlets produced by Liphatech indicate that little effort is needed to meet the Rozol label requirement for carcass searches and disposal of prairie dogs carcasses (Bruesch 2009, Liphatech 2009). These pamphlets, made available during the time when the Rozol label required two return visits for carcass searches, indicated that Rozol was less labor intensive than a competing

rodenticide labeled for use on prairie dogs that did not require carcass searches or in-burrow application. Bruesh (2009) makes the recommendation to "allow a little extra time for carcass search and recovery" when using anticoagulant rodenticides to control prairie dogs. Both pamphlets imply that the requirement to conduct two carcass searches and properly dispose of bait and carcasses found above ground is less labor intensive than a single pre-baiting trip and the potential need to reapply a competing rodenticide (Bruesch 2009, Liphatech 2009). Quick searches that lack systematic protocols are expected to find fewer poisoned carcasses than those that include walking transects of specified width (e.g., Lee and Hygnstrom 2007, Vyas 2010a, Witmer et al. 1995). Furthermore, Vyas (2010a) observed dying BTPDs on his last search 29 days after an application. Thus, applicators that cease carcasses searches after 2 weeks if no animals are found, as specified on the label, would miss later mortalities as indicated by Yoder (2008). We believe that, although Rozol-exposed prairie dogs may be found dead or debilitated on the surface of a colony for at least a month following application, searches as described on the label are inadequate to consistently locate poisoned prairie dogs above ground and thus unlikely to prevent non-target exposure.

Though we note that follow-up search protocols may not always be followed, the Service believes that current Rozol label directions to reduce secondary exposure by collecting and disposing of dead and dying prairie dogs at 1- to 2-day intervals late in the day are inadequate to protect non-target species. While the label specifies a search frequency, it does not specify protocols how to conduct the searches. A random search pattern, which would be the likely categorization for the current Rozol label searches, is poor in detecting target and non-target animals (Witmer et al.1995). Searcher efficacy in locating dead animals is significantly increased if transect patterns are employed to search for animals (Witmer et al. 1995). That same study showed that searcher effectiveness when using protocols for walking transects or circular subplots ranged from 24.5 – 36.2 percent compared to just 2.6 percent when using a random search pattern protocol (Witmer et al. 1995). Systematic searches, such as transect-line searches spaced at appropriate intervals, increase detection of poisoned prairie dogs and non-targets (Lee and Hyngstrom 2007, Vyas 2010a).

Many prairie dogs are likely scavenged prior to the opportunity for removal by applicators. Carcass retrieval studies, aimed at evaluating pesticide mortality events, have found that as high as 92 percent of carcasses are scavenged within 24 hours and that carcass removal by scavengers is more rapid in areas of higher carcass density than in lower density kills because clumped food sources can attract scavengers (Vyas 1999). Thus, even if the label is followed and applicators remove carcasses at 1- to 2-day intervals late in the day, it is unlikely to outpace removal by scavengers. Further, poisoned animals are alive for an extended period of time (days to weeks) and nontarget animals in particular, may move away from the application area before they die.

We could locate no information to indicate that the current label requirements in practice prevent secondary exposure, mainly because we can locate no information that prairie dogs are being collected per the label restrictions. Furthermore, there is no indication that, if carcasses were retrieved from the surface, they would be removed from the site since the label allows prairie dogs found on the surface to be placed in prairie dog burrows or otherwise buried on site. Such carcasses could be targeted by coyotes, foxes, badgers, bears, black-footed ferrets, and other carnivores that can dig up prey or carrion.

Based on the information in this section, we conclude that few, if any, poisoned prairie dogs are removed from a colony as a result of return visits by applicators. Thus, poisoned BTPDs are likely to remain at the colony where they were poisoned and be available for consumption by federally listed species and other non-target species that federally listed species prey upon.

5. Field Study Observations of Secondary Exposure or Toxicity

As indicated previously, chlorophacinone and diphacinone toxicity share a similar mode of action; thus, we consider information on secondary exposure to non-target species from diphacinone as relevant in evaluating Rozol exposure. Four studies have evaluated chlorophacinone or diphacinone exposure to non-target species following applications to poison BTPDs (Bruening 2007, Lee and Hygnstrom 2007, Forgacs 2010, Vyas 2010a). These studies are discussed briefly below.

Field studies sponsored by Liphatech (Lee and Hygnstrom 2007, Forgacs 2010) reported little to no evidence of secondary exposure and did not observe any scavenging by avian predators. Lee and Hygnstrom (2007) performed a study designed to assess the efficacy of chlorophacinone in killing BTPDs that included searches for carcasses only on and immediately around baited plots. They found 10 carcasses above ground (9 BTPDs and a cottontail rabbit) at a ratio of 1 carcass found per 14 acres searched. Forgacs (2010) quantified the number of dead and dying prairie dogs above ground following a field application and included searches on three test plots consisting of approximately 24 acres for 21 days after application. They did not find any dead prairie dogs or non-target carcasses; however, the study was performed in early February and included precipitation and storm events that the researchers believe limited the prairie dog activity above ground and the ability of the researchers to return to the sites to search for prairie dogs (Forgacs 2010). According to a field study sponsored by Scimetrics, the registrant for Kaput Prairie Dog Bait (diphacinone active ingredient), sick and lethargic prairie dogs were observed above ground following a field application, and researchers also observed a bald eagle flying off the treatment plot with a prairie dog in its talons (Bruening 2007).

A study sponsored by the Service and performed by the U.S. Geological Survey (Vyas 2010a) documented avian and mammalian non-target exposure and effects following a field application of Rozol. Signs of exposure reported in this study included mortality, morbidity, discolored droppings, scavenging, possible blood stained soil, and a general change in the number of BTPDs and other wildlife (Vyas 2010a). Carcass searches were conducted over an area of approximately 43 acres for 14 days over a 29-day post-application period and recovered 2 intact 13-lined ground squirrels (*Spermophilus tridecemlineatus*), 9 intact BTPDs, 7 scavenged BTPDs, and 1 intact western meadowlark (Vyas 2010a). The meadowlark had abundant hemorrhaging in the pectoral muscle, one focal hemorrhage in the brain, and chlorophacinone was detected in the liver and lower gastrointestinal contents (Vyas, pers. comm., 2010). Meadowlarks are a recognized food source for the federally endangered northern aplomado falcon (FWS 2002b). Raptors were also seen visiting the poisoned prairie dog colony and foraging on BTPDs (Vyas 2010a).

A Rozol application in South Dakota on a prairie dog colony in 2005 found approximately 400-500 dead and dying prairie dogs on the surface when a 160-acre densely populated prairie dog town was treated with Rozol (Golden and Gober 2010). The South Dakota incident was investigated by the EPA and confirmed to be related to an application of Rozol. At that time, Rozol was not authorized for use in South Dakota and a subsequent investigation by the EPA ensued, but the outcome is not available at this time.

In December 2006, a deceased adult female bald eagle was recovered by Service Law Enforcement and submitted to the National Fish and Wildlife Forensics Laboratory in Ashland, Oregon (FWS 2007a). The necropsy revealed that poisoning with chlorophacinone and physical trauma had occurred. The laboratory report concluded that "the observed small hemorrhagic skin laceration on the dorsal elbow region of the right wing was caused by trauma from an undetermined source. This trauma may have initiated the extensive hemorrhaging caused by the presence of the anticoagulant rodenticide in the eagle." Chlorophacinone was detected in the bald eagle's liver at 0.30 µg/g ww, a concentration similar to that detected in the liver of another bald eagle (0.40 µg/g ww, as described below) and considered indicative of chlorophacinone poisoning (FWS 2011b). The Service Special Agent working on the Nebraska bald eagle mortality case interviewed a licensed applicator regarding the incident. The applicator remarked that even when label directions for Rozol applications are followed, BTPDs are often seen above ground in a moribund state of stupor that leaves them vulnerable to capture or predation (FWS 2007a).

In January 2009, a sub-adult female ferruginous hawk and an adult male great-horned owl (*Bubo virginianus*) were collected by Service Law Enforcement and submitted to the National Fish and Wildlife Forensics Laboratory in Ashland, Oregon (FWS 2009c). Both raptors had a liver chlorophacinone concentration of 0.25 µg/g ww and were found in an area in Kansas where Rozol was being used to control prairie dogs. The ferruginous hawk had prairie dog hair in its stomach contents, and the owl's stomach contents had hairs from rodents and/or insectivores (Rodentia; Soricomorpha).

In March 2011, another bald eagle carcass was opportunistically recovered in Nebraska and analyzed by the National Fish and Wildlife Forensics Laboratory. The bald eagle's cause of death was diagnosed as ingestion of chlorophacinone due to a liver chlorophacinone concentration of 0.4 µg/g ww and hemorrhage of the subcutaneous tissues, body cavities and lungs (FWS). According to the examiner, "no gut contents were available for examination, but toxicity was likely incurred through ingestion of one or more poisoned rodents." Prairie dog colonies were in the general vicinity of where the bald eagle was recovered, and the law enforcement case is still under investigation.

Based on the reports described above (Lee and Hygnstrom 2007; FWS 2007a, 2009c; Bruning 2007; Vyas 2010a), we conclude that chlorophacinone exposure to federally listed species and non-target animals following field applications of Rozol has occurred in the past and is likely to occur in the future if Rozol is used to poison BTPDs under the current label directions.

D. REVIEW OF THE EPA'S ROZOL EFFECTS DETERMINATION

We believe that risk calculations in the EPA's BA likely underestimate risk to non-target species (described in detail below). Therefore, the analysis in this section informed the development of this BO and serve as feedback to the EPA for consideration in developing future effects determinations for listed species.

a. Underestimated Risk to Avian Species

A Risk Quotient (RQ) is equal to the Estimated Environmental Concentration (EEC), a term used to estimate exposure, divided by the relevant toxicological endpoint or Toxicity Reference Value (TRV). The BA provides a RQ of 0.104 for avian species, a value that barely exceeds the EPA's Level of Concern (LOC) of 0.1 (EPA 2010b). The TRV used to calculate this RQ is based on dietary median Lethal Concentration (LC_{50}) for northern bobwhite (*Colinus virginianus*) quail. Although the EPA's selection of a sub-acute dietary LC_{50} test value for the TRV is preferred to a single dose LD_{50} value, this TRV is still likely to underestimate risk to avian species. As dietary LC_{50} results can be highly dependent on a species' willingness to eat the bait and their ability to cope with reduced nutriment, their applicability in quantitative risk assessment has been questioned (Hill 1993, Mineau et al. 1994, Hoffman 2003). In addition, data suggest that the northern bobwhite quail, which eats primarily insects and vegetation, is not likely to be representative of other more sensitive avian species, especially those that prey upon and scavenge prairie dogs or other non-target small animals. Though toxicity data are lacking for chlorophacinone effects to a wide breadth of species, recent investigations have found that sensitivity of raptors to the closely related indandione rodenticide diphacinone is much greater than predicted from test species used in pesticide registrations. Acute diphacinone toxicity tests indicate that American kestrels (*Falco sparverius*) are over 20 times more sensitive than northern bobwhite quail and over 30 times more sensitive than mallard (*Anas platyrhynchos*) ducks, 2 test species required by the EPA for pesticide registration (Rattner et al. 2010a and 2011b). Golden eagles (*Aquila chrysaetos*) appear to be even more sensitive to diphacinone than kestrels (Savarie et al. 1979, Rattner et al. 2011b). Given the similarity of chlorophacinone to diphacinone, we conclude that at least raptors (e.g., the northern aplomado falcon), and possibly other groups of species, will likely exhibit greater sensitivity than can be estimated from existing mallard or northern bobwhite quail studies.

Furthermore, the LC_{50}-based TRV does not account for potential sub-lethal effects of chlorophacinone that can decrease listed species' survival and/or reproduction. Accounting for sub-lethal effects from chlorophacinone exposure such as fatigue, clotting abnormalities, and hemorrhaging is important when evaluating risk to federally listed species. This is especially true when evaluating cumulative effects that include sub-lethal effects from exposure to chlorophacinone as well as other environmental stressors such as adverse weather, food shortages, and predation (Vyas et al. 2006). The BA identifies external bleeding, internal hemorrhaging, and increased blood coagulation time as sub-lethal effects to avian species from secondary exposure to chlorophacinone-poisoned food; however, other sub-lethal effects (e.g., fatigue) can occur even prior to gross observation of internal and external bleeding. As mentioned previously, chlorophacinone uncouples oxidative phosphorylation, and studies have reported that the first observed signs of secondary chlorophacinone toxicity in raptors include

fatigue such as wing-drooping (Radvanyi et al. 1988). Fatigue induced from chlorophacinone exposure is expected to substantially reduce a listed species' ability to capture prey and thus negatively affect its reproduction and survival in the wild.

Sub-lethal effects have been documented in raptors exposed to anticoagulants and those effects can occur despite low tissue residue concentrations. For example, American kestrels administered diphacinone had liver residues just above the detection limits of 0.263 and 0.280 µg/g ww diphacinone, but histological evidence revealed hemorrhages in lung and liver tissues (Rattner et al. 2011b). Golden eagles fed muscle from diphacinone-treated sheep exhibited extreme weakness, ataxia (lack of muscle control), and hemorrhages (Savarie et al. 1979). These studies indicate that raptors are susceptible to indandione's multiple modes of action. Although some avian species have survived laboratory studies after being fed anticoagulant poisoned rodents until time of euthanasia (Savarie et al. 1979, Mendenhall and Pank 1980, Radvanyi et al. 1988), sub-lethal effects described in these studies (e.g., fatigue; wing-drooping; and lung, heart, and liver hematomas) are expected to result in decreased survival or reproduction under field conditions. A comprehensive assessment of potential effects of chlorophacinone exposure to sensitive populations of migratory birds has not been completed, and reliance on labeled use restrictions does not protect vulnerable species (Golden and Gober 2010). Thus, in addition to the avian reproduction study that the EPA has required Liphatech to complete, we have recommended that the EPA exercise their authority under the FIFRA to require additional field assessments that include tracking avian predators and scavengers (e.g., ferruginous hawks, eagles) that are expected to be the most susceptible to Rozol use in prairie dog towns (Schwarz and Gober 2011). Until such studies are completed to provide data on sub-lethal effects and subsequent reproduction and survival, it is difficult to evaluate the secondary toxicity risk of Rozol exposure to federally listed species such as the northern aplomado falcon.

An acute exposure to listed species from a one-time feeding of chlorophacinone bait or poisoned prey may still result in death or harmful sub-lethal effects because even minor increases in fatigue in predators can undermine their ability to acquire prey. However, as the EPA indicated in the BA, there is high potential for chronic effects to occur in birds because LD_{50} and LC_{50} data indicate that acute environmental exposures can result in doses that do not result in immediate direct lethality but instead create potential for long-term exposures and chronic toxicity. The potential for chronic exposure to birds is further increased by the potential for exposure to other anticoagulant rodenticides (e.g., diphacinone) and by repeated exposures to chlorophacinone and diphacinone from multiple applications and at multiple locations as the species forage over large home ranges and migrates. One of the other diphacinone products to control BTPDs is Kaput®-D, which was previously available for use from October 1 to March 15 under a FIFRA Section 24c registration in Colorado, Kansas, Nebraska, Texas, and Wyoming and has a pending request for registration for use throughout the BTPD's range (Golden and Gober 2010). Previous studies indicate that anticoagulant rodenticides have a wide geographic use and detection of one or more of these compounds in the livers of predatory birds is common (Stone et al. 2003, Albert et al. 2010). Therefore, it is a reasonable assumption that raptors such as the northern aplomado falcon may already be carrying an anticoagulant burden and are thus more susceptible to adverse effects from additional exposure.

b. Prairie Dog Chlorophacinone Residues

In its BA, the EPA uses a maximum carcass whole-body residue value of 2.24 µg/g ww for the Environmental Effects Concentration in evaluating secondary risk to species that consume poisoned BTPDs; however, this value may underestimate exposure. The prairie dog with a carcass concentration of 2.24 µg/g ww had a liver concentration of 6.66 µg/g ww and was collected an unknown number of days after bait application. It is also unknown whether this prairie dog had recently consumed bait or stopped eating bait days before it died. Currently, data exists for BTPD carcasses that were picked up 10 to 25 days after a field application (Lee and Hygnstrom 2007, Primus 2007), but it is unclear if they still had bait in their system or if they became too sick and stopped eating bait days before they died. Lab data also exists for BTPDs that consumed a single dose (53 grams bait) and were euthanized periodically after being maintained on a clean diet (Witmer 2011). Prairie dogs in the Witmer (2011) study that had most recently consumed bait had the highest liver and carcass concentrations of chlorophacinone. However, for field applications, there may be 10 or more LDs_{50} distributed per individual prairie dog (based on 3.9 active burrows per prairie dog as explained previously) and a longer lag time between exposure and death. Thus, prairie dogs likely continue to eat Rozol after they have consumed a LD_{50}. These prairie dogs likely have higher chlorophacinone residues, especially in the liver, than those that die several days after they stop eating bait (Pitt et al. 2005, Witmer 2011).

The use of whole-body chlorophacinone residues, as opposed to chlorophacinone residues in liver, may underestimate secondary exposure risk to non-target wildlife, particularly scavenging and predating birds. The EPA's BA does not account for concentrations of chlorophacinone in internal organs, such as liver, which may be selectively consumed by certain predators or scavengers and livers generally much greater concentrations than whole-body samples. Eight BTPD carcasses collected after a field application of chlorophacinone bait had a mean concentration of chlorophacinone in liver of 5.86 ± 1.88 µg/g ww (maximum of 6.66 µg/g) compared to a whole body mean concentration of 1.48 ± 0.46 µg/g ww (maximum of 2.24 µg/g) (Primus 2007). Use of a liver concentration instead of a carcass concentration may be more appropriate based on feeding behavior of some animals that selectively eat parts of prairie dogs. For instance, some predators may only forage on the most readily accessible body cavity organs, including the liver (Figure 2). When multiple carcasses or moribund prairie dogs are readily available, internal organs may also be preferentially selected over other less accessible or digestible prairie dog body parts. A realistic worst-case scenario would include a maximum liver concentration for the EEC, as opposed to the maximum whole body residue used in the BA. The highest liver known chlorophacinone concentration in a BTPD is 8.4 µg/g ww in a BTPD that consumed 52.8 grams of Rozol and was euthanized 2 days later (Witmer 2011). We recognize that data for chlorophacinone concentrations in livers from prairie dogs is extremely limited; thus, liver concentrations of 8.4 µg/g ww from a euthanized prairie dog and 6.6 µg/g ww from a dead field collected prairie dog are unlikely to be the greatest concentrations encountered if more than a few dozen prairie dog livers are examined.

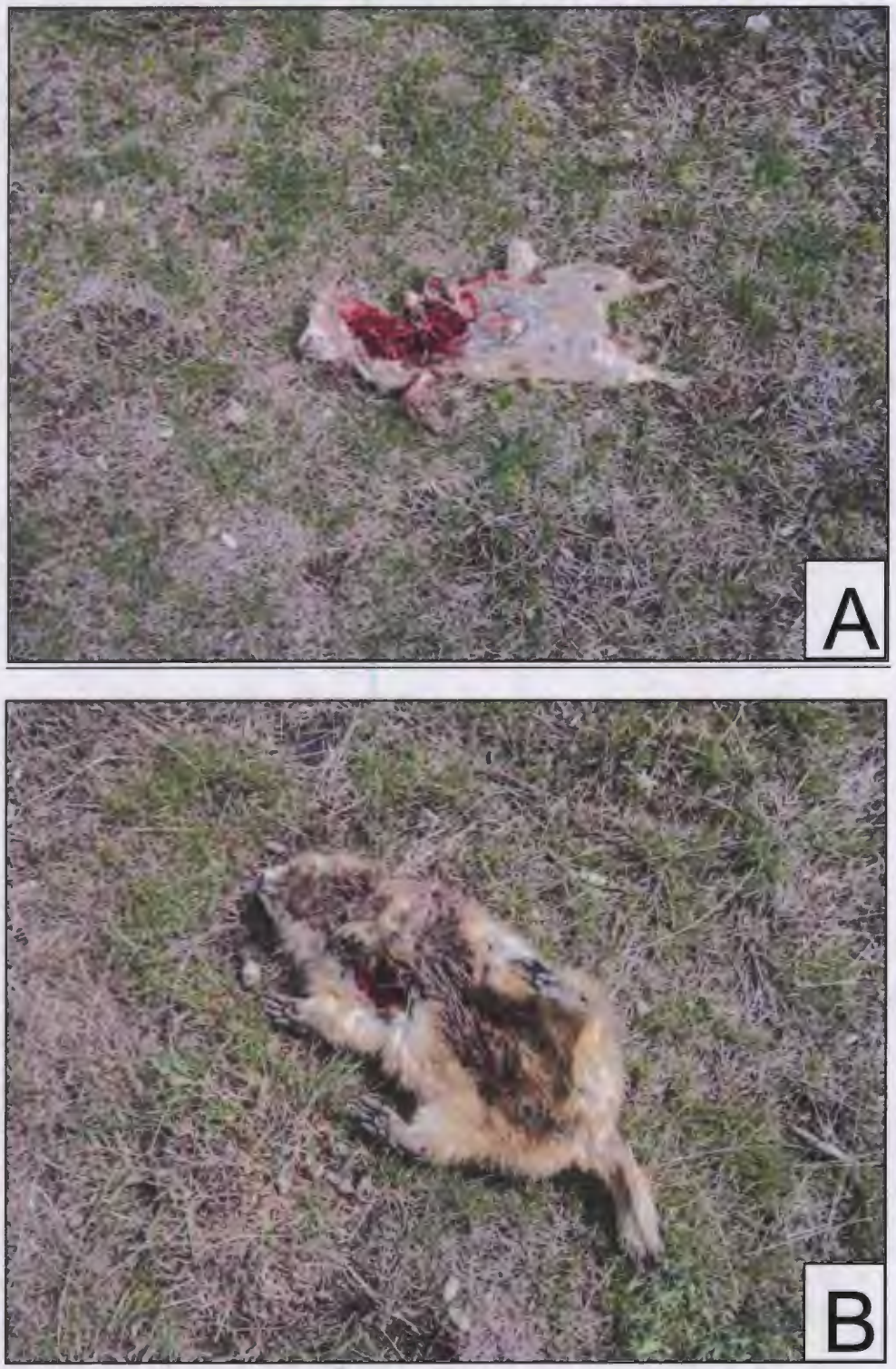


Figure 2. BTPDs (A and B) scavenged at a prairie dog colony in 2005 after an application of Rozol. Note selective feeding by scavengers that target internal body organs.

c. Risk Quotient Calculations and Uncertainty

A review of the BA by Liphatech (2010) critiqued it for not correctly accounting for a "high degree of uncertainty in the resulting Risk Quotient calculations." We agree with this assessment, but for different reasons. Liphatech requested uncertainty be considered given the use of what they termed as "extreme" data for non-target species and prairie dog carcass residues. We disagree that extreme data was used and, for reasons specified above, believe that TRVs selected for non-target species and residue values in prairie dogs used by the EPA are both too low to represent a realistic worst case scenario. Contrary to Liphatech's concern for RQs being too high due to unaccounted uncertainty, several lines of evidence regarding Rozol exposure and effects suggest that the calculated RQs should be greater to account for uncertainty and missing data. For example, as calculated in the BA, the RQ derived from the BTPD whole-body concentration of 2.24 µg/g ww does not exceed the LOC for secondary toxicity to avian species (EPA 2010b page 80, Table 5.1). Not only are greater exposure estimates warranted that increase the EEC, based on consumption of chlorophacinone concentrations in liver, but also the TRV is overestimated based on the use of acute toxicity tests rather than chronic or sub-acute tests and differences in species' sensitively as explained above. Both an increased EEC and decreased TRV would result in a greater RQ. Further, the EPA's RQ calculations in the BA do not specifically address uncertainty from the influence of environmental stressors that can make non-target animals more susceptible to poisoned food (e.g., adverse weather conditions, food shortages, migration, and predation).

Uncertainty factors are recommended for use in risk assessments to protect federally listed species as scientifically appropriate or where available data are incomplete or otherwise warrant its application (EPA 1995 and 2011d). For Rozol, all three reasons to include uncertainty factors are valid. According to the EPA technical guidance, reasonable uncertainty factors may range from 1-100 for interspecies uncertainty, 1-10 for intraspecies variability, and 1-10 for sub-acute to chronic toxicity (EPA 1995). In the case of chlorophacinone, information from closely related pesticides indicate that interspecies sensitivity could be as much as 20 or 30 times greater than toxicity values measured in test species (Rattner et al. 2010a, 2011b). Reported mortality incidents involving raptors described herein support the likelihood that these taxa can be killed from exposure to chlorophacinone through Rozol use. If the BA applied uncertainty factors for interspecies sensitivity alone, then RQs based on chlorophacinone concentrations in BTPDs would exceed the LOC and be more in accordance with our concerns for secondary exposure to birds and mammals that consume Rozol-poisoned prairie dogs.

In addition, RQs were not calculated for chronic or sub-lethal effects to federally listed birds, presumably due to the lack of registrant-submitted reproduction studies. In the absence of data, a lack of effects cannot be assumed, but available lines of evidence must be examined to determine if effects can be reasonably ruled out. In the case of Rozol, chronic exposure to anticoagulant rodenticides is likely for predatory and scavenging species which can cause death or sub-lethal effects that may hasten death when combined with other stressors (Stone et al. 1999). These effects are likely to occur at concentrations below those which would produce lethality in a laboratory setting and therefore must be considered as distinct endpoints. Where data are lacking to produce quantitative RQs with much certainty or assign numeric uncertainty factors, a preferred option is to express risk in qualitative terms. Professional judgment or other qualitative

evaluation techniques are appropriate for ranking risks into categories such as low, medium, and high when exposure and effects data are limited or are not easily expressed in quantitative terms (EPA 1998b). For the New Mexican ridge-nosed rattlesnake, for example, the EPA determined that adverse effects were likely even though both RQs were below the LOC because chronic effects could occur. Thus, the Service agrees with the EPA's conclusion that chronic effects cannot be ruled out based on the available data. The EPA's decision to ultimately base adverse effects determinations not solely on RQs but on the uncertainty surrounding chronic effects that could result in growth, survival, and reproductive impairments that are detrimental to species recovery we believe was appropriate.

E. WILDLIFE MORTALITY INCIDENTS

Due to the sensitivity of testing Rozol on listed species, we have no direct information on the effects of Rozol to the species under consultation. Therefore, we look to studies of effects of Rozol on other non-target species to inform our analysis. We characterize these studies in this section.

Based on sub-lethal effects to non-target species as reported from laboratory studies as well as reported mortalities and concerns based on opportunistic field recoveries (Erickson and Urban 2004, FWS 2007a, EPA 2010b, Ruder et al. 2011), there is a need for field studies that evaluate anticoagulant exposure and effects to the many species that consume anticoagulant poisoned prairie dogs and other primary consumers. Although a lack of incident reporting is likely a factor in addressing risk uncertainty (Erickson and Urban 2004), wildlife mortality incidents involving chlorophacinone reported to the EPA include bald eagles, a red-tailed hawk, turkeys, coyotes, San Joaquin kit foxes, grey squirrels, and a bobcat (Erickson and Urban 2004, FWS 2007a). It is noteworthy that the bobcat had a liver concentration of 0.4 µg/g ww chlorophacinone (a concentration similar to other non-target species that are believed to have died from chlorophacinone exposure (FWS 2007a, 2011b)) and apparently died from tertiary exposure to chlorophacinone as it was found dead 1 day after seen feeding on a dead owl that contained a rodent carcass in its crop (Erickson and Urban 2004, EPA 2010b).

Ruder et al. (2011) reported three mortality events in Kansas involving several species, including wild turkeys (*Meleagris gallopavo*), a raccoon (*Procyon lotor*), and an American badger (*Taxidea taxus*). In all three cases, chlorophacinone was detected in the liver of the non-target species. The first incident in 2002 included the death of 1 wild turkeys found 2.5 weeks after a Rozol application; concentrations of chlorophacinone in their livers were 0.69 and 0.40 µg/g (Ruder et al., 2011). The second incident in 2009 included 45 dead turkeys from exposure to zinc phosphide as well as a raccoon with liver concentrations of chlorophacinone, brodifacoum, bromadiolone, and diphacinone of 1.4 µg/g, 0.5 µg/g, 0.37 µg/g, and trace, respectively. The authors suspected that the raccoon exposure to brodifacoum, bromadiolone, and diphacinone was from the use of over-the-counter rodenticides against commensal rodents (Ruder et al., 2011). The badger was found within an area in western Kansas where Rozol had been used and had a high chlorophacinone concentration of 4.4 µg/g ww in its liver (Ruder et al., 2011). The authors concluded that their opportunistic findings of non-target species mortalities likely underestimate actual non-target species losses. This conclusion seems justified as a 4-year survey of

anticoagulant poisonings of wildlife in France based on a wildlife disease surveillance network yielded 59 confirmed diagnoses for bromadiolone and 41 for chlorophacinone, indicating that chlorophacinone is frequently detected in non-target species (Berny et al. 1997).

In addition to the opportunistic wildlife mortality incidents noted above, there are likely many more individuals and non-target species poisoned from chlorophacinone that have not been found. As mentioned previously, carcass-detection studies have found that even when searches are performed in areas known to contain carcasses, a significant percentage will never be found due to scavenging, size or coloration that renders the carcass inconspicuous, or field conditions such as remote, inaccessible areas, that impede searches (Vyas 1999). In the case of anticoagulants, the delayed toxicity can temporally or geographically distance the carcass from the application area (Colvin et al. 1988). In addition, exposure to chlorophacinone may result in sub-lethal effects that occur at concentrations below a diagnostic threshold for lethality, masking their role in mortality incidents where acute lethal hemorrhage is not the proximal cause of death and may be attributed to causes such as trauma or disease (Stone et al. 1999).

Opportunistic recoveries indicate that raptors may be at high risk to secondary toxicity from chlorophacinone use to poison BTPDs. As described in the "Rozol Exposure Assessment" above, Service Law Enforcement recovered two bald eagles in Nebraska and a great horned owl and ferruginous hawk in Kansas which died following chlorophacinone exposure (FWS 2007a, 2009c, 2011b). More dead raptors were found in that same area of Kansas after Rozol was used to control prairie dogs in 2009, including two more ferruginous hawks and a bald eagle that were found shot and thus not tested for chlorophacinone (FWS 2009c). Also in that same area of Kansas, Audubon of Kansas reported that, in addition to the raptors provided to Service Law Enforcement in 2009, they had found an additional 17 dead hawks, mostly ferruginous hawks that were not picked up in the field. It is not firmly established whether the raptor mortalities are attributed to chlorophacinone or Rozol as no definitive testing for chlorophacinone in body tissues was conducted on the raptors; however, the opportunistic finding of the raptors coincided with Rozol applications nearby.

Migratory raptors are especially susceptible to secondary poisoning from anticoagulant use due to their propensity to feed in prairie dog colonies (Golden and Gober 2010). Raptors are believed to be especially susceptible to secondary poisoning from Rozol given the likelihood that they can spot dead or dying BTPDs that are more difficult to see from a ground level perspective (Vyas 2010b) and raptors have been observed to be attracted to Rozol poisoned BTPD colonies (Vyas 2010a). The golden eagle, ferruginous hawk, and burrowing owl are among nine species with documented dependence on prairie dog colonies (Kotliar et al. 1999, Seery and Matiatos 2000). All three of these raptor species have been identified as "Species of Conservation Concern," defined as species that are likely to become candidates for listing under the ESA without additional conservation action (FWS 2008a). Further, bald and golden eagles are protected under the Bald and Golden Eagle Protection Act. In particular, ferruginous hawks and golden eagle populations appear to be experiencing declines throughout most of their range, and the availability of poisoned prey, which occurs when anticoagulants are used for prairie dog control, are expected to exacerbate population declines. Golden eagle populations may not be able to withstand additional loss of individuals (FWS 2009d, Golden and Gober 2010). Bald eagles have a kleptoparasitic association with ferruginous hawks (whereby eagles pursue

ferruginous hawks and steal their prey) which are an efficient predator of prairie dogs (Jorde and Lingle 1988). Thus, both species may be particularly vulnerable to anticoagulants use to kill BTPDs (Golden and Gober 2010). This suspected vulnerability is further supported by the opportunistic recovery of two bald eagles killed from chlorophacinone exposure previously described and the abundance of dead ferruginous hawks reported by Audubon of Kansas from an area where Rozol was being used to poison prairie dogs. Migratory bird deaths attributed to chlorophacinone poisoning are not permitted or authorized under the Migratory Bird Treaty Act (MBTA).

The Service is gaining a better understanding of the Rozol label requirements regarding multiple return visits to retrieve dead and dying prairie dogs and exposed bait. Based on the information provided by the EPA and for reasons explained above, we believe the label requirements do not prevent exposure to migratory birds or may be impractical or not implementable. Rozol use on BTPDs is expected to result in take of migratory birds, including federally listed species such as the northern aplomado falcon.

As noted earlier, Rozol use on BTPDs was determined to have killed a bald eagle in 2006, when that species was protected under the ESA, which prohibits unauthorized taking of federally listed endangered or threatened species. In accordance with the bald eagle post-delisting monitoring plan (FWS 2010b), the bald eagle monitoring team continues to track new and potentially significant sources of bald eagle mortality. Since Rozol was authorized for BTPD control in 2006, there have been two bald eagle deaths attributed to chlorophacinone poisoning in Nebraska. We consider Rozol use on BTPDs as a new and potentially significant source of mortality to bald eagles from secondary poisoning that can occur when a bald eagle eats dead or dying prairie dogs that have been poisoned with Rozol.

F. SUMMARY OF ROZOL EXPOSURE AND EFFECTS RELEVANT TO ALL LISTED SPECIES ADDRESSED IN THIS BIOLOGICAL OPINION

- Toxic effects from chlorophacinone exposure include fatigue and increased permeability of capillaries resulting in systemic internal hemorrhaging prior to death. There is no evidence of taste aversion to Rozol; thus, non-target species may continue consumption until they receive a LD_{50}, or they may suffer from sub-lethal effects. Sub-lethal effects could result in death when combined with other stressors (e.g., temperature, predation, trauma, food scarcity, migration), or growth and reproductive impairments could be detrimental to species' recovery.
- Chlorophacinone is most toxic when animals are exposed to multiple doses for multiple days. Thus, current required acute standardized toxicity tests for chlorophacinone greatly underestimate risk to non-target animals.
- According to the EPA, mobility from Rozol bait into soil or water is considered a negligible exposure pathway to non-target organisms, and that chlorophacinone is expected to remain undegraded in bait. Actual consumption of bait and consumption of poisoned animals is the primary environmental dissipation pathway for Rozol. We agree with the EPA on those points.

- Based on the label application rate, excessive LDs_{50} per BTPD are likely applied and result in increased risk to non-target species. In addition to having excess bait available for direct consumption by non-target species, over-application and Rozol's prolonged toxic mode of action may result in a high risk of secondary exposure to non-target species, especially those species attracted to poisoned BTPD colonies. A 6-month application season for Rozol can result in a long duration and increased opportunity for repeated exposure to chlorophacinone and/or diphacinone rodenticides as the species migrates or moves within their territory.
- Despite current label restrictions and requirements, previous studies and observations indicate that Rozol is available to non-target species by both primary and secondary exposure routes and may even result in tertiary poisoning. A label search protocol that does not specify how to conduct carcass searches will likely result in random search methods that are far less efficient than standard line-transect search methods. Further, label requirements aimed at reducing exposure to non-target species that are based on return site visits for weeks after the application to pick up dead and dying prairie dogs and bait may be impractical. Burying prairie dogs on the colony may not be effective at preventing exposure to non-target species that can dig up carcasses or feed on poisoned prey between carcass searches.
- RQs derived in the EPA's BA underestimate non-target species risk to Rozol because they are: a) based on study protocols that consider limited (1- to 5-day) exposures in the lab; b) do not account for information indicating that raptors may be 20-30 times more sensitive than standard avian test species such as quail and ducks; c) do not attempt to quantify known sub-lethal effects; and d) do not consider higher concentrations of chlorophacinone in the liver, especially for species that may selectively consume internal organs instead of whole-body tissues.
- Although wildlife mortality incidents are underreported and surveillance efforts are lacking, opportunistic recoveries of non-target species exposed to chlorophacinone include: bald eagles, hawks, owls, turkeys, meadow lark, pigeons, coyotes, kit foxes, raccoon, badger, squirrels, and a bobcat.
- Opportunistic recoveries have shown that Rozol use on BTPDs has killed non-target species protected under the ESA, MBTA, and the Bald and Golden Eagle Protection Act. Many of these species (e.g., bald eagles, golden eagles, ferruginous hawks, American kestrels, owls) appear to be especially susceptible to Rozol toxicity and are expected to continue to die from Rozol exposure given current label use restrictions.

VI. GENERAL CONSERVATION RECOMMENDATIONS

Section 7(a)(1) of the ESA directs Federal agencies to utilize their authorities to further the purposes of the ESA by carrying out conservation programs for the benefit of endangered and threatened species. Conservation recommendations are discretionary agency activities to minimize or avoid adverse effects of a proposed action on listed species or critical habitat, to help implement recovery plans, or to develop information. Based on the above discussion of Rozol's mode of action, its environmental fate and effects and known exposure routes and risks to nontargets animals we believe it is important identify conservation recommendations that address those concerns. Accordingly, we provide the following conservation recommendations for EPA's consideration that are within your authorities and will further the purposes of the ESA

and benefit the listed species in this consultation.

A. If the EPA chooses to continue registration of Rozol and other anticoagulants for use on prairie dogs, it should first develop alternative testing protocols to evaluate their toxicity to non-target species. The currently required standardized toxicity tests for chlorophacinone greatly underestimates risk to non-target species because indandiones are much more lethal when multiple doses are consumed over multiple days as opposed to a one-time feeding. We recommend future assessments for first generation indandione rodenticides are modified to include multiple-day exposures tests that measure individual daily dosage and responses. This would complement the current required avian oral test and dietary lethality tests. Additionally, protocols should be designed to evaluate sub-lethal effects by including observational periods, sensitive blood clotting assays (Rattner et al., 2010b), gross pathology and microscopic examination of tissues (histopathology).

B. If the EPA chooses to continue registration of Rozol or other anticoagulants for use on prairie dogs, it should first study how to prevent secondary poisoning of predators and scavengers that may feed upon dead and dying prairie dogs. The results of such studies should be used to modify the label.

C. If the EPA chooses to continue registration of Rozol or other anticoagulants for use on prairie dogs, it should first study detrimental effects to raptors and other wildlife that consume dead and dying prairie dogs. Thus, in addition to the avian reproduction study that the EPA has required Liphatech to complete, we recommend that the EPA exercise their authority under FIFRA to require additional field assessments that include tracking avian predators and scavengers that are expected to be most susceptible (e.g., ferruginous hawks, eagles, canines) to Rozol poisoning from applications at prairie dog towns. Such information would benefit our evaluation of the endangered northern aplomado falcon, gray wolves, and other predators and scavengers if those species were to become federally listed under the ESA.

D. If the EPA chooses to continue registration of Rozol or other anticoagulants for use on prairie dogs, it should not rely on quail and mallards as the test species for development of anticoagulant risk assessments. These species do not reflect the risks to raptors which can be 20 to 30 times more sensitive than these species. Further, raptors are the likely avian species that will exposure risk from Rozol applications to BTPDs. We recommend that risk assessments for anticoagulants include measures to assess harmful effects to the likely affected bird guild. Raptors and scavengers are those likely end-point species, and the Rozol risk assessment should reflect that.

E. If the EPA chooses to continue registration of Rozol or other anticoagulants, the EPA should conduct tests to determine the minimum amount of product that should be applied to accomplish the intended task.

F. Given our concerns with secondary toxicity, we encourage the EPA and Liphatech, Inc. to support Integrated Pest Management (IPM) education and outreach to applicators. An IPM approach could prevent unnecessary applications when good alternatives to pesticides exist. Guidance on how to perform IPM should be accessible on the EPA's *Bulletins Live!* online site.

VII. SPECIES ANALYSES

A. OVERVIEW

On September 9, 2011, we agreed with the EPA's analysis that Rozol use on BTPD towns is likely to adversely affect listed species and critical habitats (FWS 2011c). As explained in the "Description of the Action" section above, additional coordination during the formal consultation process resulted in the EPA's adoption of conservation measures to avoid or reduce adverse effects to some listed species and their critical habitats. However, conservation measures were not necessary for all species. Among those species/habitats for which conservation measures were not developed, the Service conducted additional review after submitting our September 9, 2011, letter to the EPA and found that adverse effects are not likely for the American burying beetle, black-capped vireo, Canada lynx, Eskimo curlew, golden-cheeked warbler, gulf-coast jaguarondi, ocelot, piping plover, and whooping crane (Table 1). This conclusion is generally due to lack of overlap in range of the species or critical habitat with the range of the BTPD or lack of common use by the species of habitats occupied by the BTPD. For those species, the risk of Rozol exposure and effects is considered highly unlikely and therefore adverse effects are not expected to occur.

The adopted conservation measures in the EPA's December 13, 2011, letter have been agreed to by Liphatech, Inc. and will be incorporated into County Bulletins via the EPA's *Bulletins Live!* as part of the Rozol label before October 1, 2012 (EPA 2011c). Those measures are reiterated in the "Description of the Action" section above and have removed or reduced the risk of adverse impacts to several listed species. The analyses herein for the black-footed ferret, Chiricahua leopard frog, grizzly bear, jaguar, (Mexican) gray wolf, Mexican spotted owl, New Mexico ridge-nosed rattlesnake, and PMJM are based on these conservation measures.

We provide more in-depth analysis for the black-footed ferret, gray wolf, and northern aplomado falcon because conservation measures were unable to entirely preclude adverse effects to these species, although the conservation measures did reduce impacts and, in the case of the black-footed ferret, did so significantly. The analyses for black-footed ferret, gray wolf, and northern aplomado falcon includes species and habitat information, environmental baseline, effects of the action, cumulative effects, conclusions regarding jeopardy or destruction/adverse modification, and associated Incidental Take Statements (ITSs) with RPMs and implementing terms and conditions.

Thus, the species/habitats analyzed for this consultation are categorized as falling into one of three groups: 1) species for which further review by the Service, after consultation was initiated, revealed that adverse effects are not anticipated; 2) species for which the EPA adopted conservation measures after initiating formal consultation, removing or reducing the risk of

adverse effects; and 3) species for which adverse effects are anticipated as a result of the proposed action, with or without conservation measures. The species and critical habitats that fall into each of these categories are listed below (Table 1).

Table 2. Summary of species determinations and page number for each species' analysis within this BO.

Species and/or Critical Habitat	Species for which No Adverse Effects are anticipated, without Conservation Measures	Species for which Conservation Measures Preclude Adverse Effects	Species for which Adverse Effects are anticipated, with or without Conservation Measures
American Burying Beetle *(Nicrophorus americanus)*	■		
Black-capped Vireo (*Vireo atricapilla*)	■		
Black-footed Ferret (***Mustela nigripes***)			■
Canada Lynx (*Lynx Canadensis*)	■		
Chiricahua Leopard Frog (*Lithobates [Rana] chiricahuensis*)		■	
Eskimo Curlew (*Numenius borealis*)	■		
Golden-cheeked Warbler (*Dendroica chrysoparia*)	■		
Gray Wolf (*Canis lupus*)			■
Grizzly Bear (*Ursus arctos horribilis*)		■	
Gulf Coast Jaguarundi (*Herpailurus (=Felis) yagouaroundi cacomitli*)	■		
Jaguar (*Panthera onca*)		■	
Mexican Spotted Owl (*Strix occidentalis lucida*)		■	
New Mexico Ridge-nosed Rattlensake (*Crotalus willardi obscurus*)		■	

Species and/or Critical Habitat	Species for which No Adverse Effects are anticipated, without Conservation Measures	Species for which Conservation Measures Preclude Adverse Effects	Species for which Adverse Effects are anticipated, with or without Conservation Measures
Northern Aplomado Falcon (*Falco femoralis septentrionalis*)			■
Ocelot (*Lepardus pardalis*)	■		
Piping Plover (*Charadrius melodus*)	■		
PMJM (*Zapus hudsonius preblei*)		■	
Whooping Crane (*Grus americana*)	■		

The details regarding the anticipated effects of the proposed action on each of the species in this consultation are provided in the analyses below.

B. SPECIES FOR WHICH NO ADVERSE EFFECTS ARE ANTICIPATED WITHOUT CONSERVATION MEASURES

Conservation measures were not developed for all species in this consultation. We have determined that, upon additional biological review, adverse effects as a result of Rozol use on BTPDs are not anticipated for nine species that did not have associated conservation measure(s). They are: 1) American burying beetle, 2) black-capped vireo, 3) Canada lynx, 4) Eskimo curlew, 5) golden-cheeked warbler, 6) Gulf Coast jaguarundi, 7) ocelot, 8) piping plover, and 9) whooping crane.

AMERICAN BURYING BEETLE

The EPA concludes in their BA that the use of chlorophacinone to control BTPDs is likely to adversely affect the American burying beetle based on direct reproductive effects.

> *The reproductive effects are due to lower carcass size in chlorophacinone treated carcasses and effects to larvae. An acute toxicity test for the earthworm (MRID 47383002) and an open literature study (Fisher et al. 2007) indicate that there is no risk to invertebrates at exposure levels relevant to this use. Furthermore, the second phase of the burying beetle study (MRID 47383001) that showed reproductive effects to burying beetles based on lower carcass weights showed that there were no direct acute effects to adult burying beetles fed chlorophacinone treated ground beef. In fact, those exposed to the chlorophacinone faired better than the control group.*

Chlorophacinone use is expected to affect reproduction of the American burying beetle through effects to emerged beetles. Number of emerged beetles is negatively affected by use of chlorophacinone poisoned carcasses in burying beetles (MRID 47383001). This type of effect is considered to be a direct effect.

The portion of the action area of concern for the American burying beetle for this consultation includes Nebraska and South Dakota where the range of this species overlaps the use of Rozol as BTPD bait. The current range known from South Dakota includes portions of Bennett, Gregory, Tripp, and Todd Counties. However, a comprehensive status survey has never been completed in South Dakota, so American burying beetles may occur in other counties with suitable habitat. In Nebraska, two disjunct populations of American burying beetles occur over much of the State. Habitats between the two populations are dissimilar with the northern Nebraska/South Dakota population occurring in the Sandhills, while the southwest Nebraska population occurs in the Loess Hills. These two populations alone contain as much as half of the known Midwest American burying beetle population and are a strong-hold for this species. The other Midwest populations (Arkansas, Kansas, Missouri, and Oklahoma) are outside of the BTPD range.

The American burying beetle is an annual species, active in the summer months, inactive during the winter months, nocturnal, and typically only reproduce once in their lifetime. They bury themselves in the soil for the duration of the winter. The young of the year overwinter as adults and comprise the breeding population the following summer (Raithel 1991). Both adults and larvae are dependent on carrion for food and reproduction. Reproductive activity commences in late May and is completed in mid-August in Nebraska and South Dakota. Per the Rozol label, chlorophacinone used on BTPD colonies is limited to October 1 through March 15. Therefore, it should not affect the American burying beetle as the species will be underground and inactive during the use window for Rozol.

In summary, we do not anticipate adverse effects to the American burying beetle from the use of chlorophacinone to control BTPDs. This conclusion is based primarily on the fact that American burying beetles are not active during the period in which the label allows the use of chlorophacinone. In addition, prairie dog carrion is not a preferred food source of American burying beetles. No critical habitat for the American burying beetle has been designated; therefore, none will be affected.

BLACK-CAPPED VIREO

The black-capped vireo is a small (12 centimeters (cm) or 4.5 inches (in.)) insect-eating songbird that was once common as far north as Kansas but is now limited largely to western and central Texas, north-central Mexico, and the Wichita Mountains of Oklahoma (Gryzbowski 1995). Black-capped vireos were federally listed as endangered in 1987. Black-capped vireos arrive in Texas from late March to mid-April (late April in dry years). They arrive in Oklahoma from mid-April to early May (mid-May in dry years). The black-capped vireo usually migrates southward from Oklahoma by late August-September and from Texas by mid-September (FWS 1991) to winter in Mexico. The black-capped vireo occurs in mixed deciduous/evergreen shrubland. Black-capped vireos require broadleaf shrub vegetation in the form of low deciduous cover (e.g., juniper and oak sp.) which is a key element in their habitat. Nests are preferentially

located in dense deciduous vegetation. Nests are placed in the fork of a variety of deciduous species with blackjack oak being preferred in Oklahoma and shin oak, Texas oak, and sumac commonly used in Texas (FWS 1991).

Black-capped vireos are insectivores during the breeding season, gleaning insects off the foliage of oaks and other deciduous trees (Graber 1961, Grzybowski 1995). The common prey items found in stomach contents include spiders and insects of the orders Lepidoptera (butterflies and moths), Coleoptera (beetles), and Hemiptera with suborder Homoptera (cicadas, aphids, planthoppers, leafhoppers, shield bugs, and others) (Graber 1961). During winter, black-capped vireos switch to an omnivorous diet, and nearly 50 percent of stomach contents sampled from western Mexico included seeds (Graber 1961).

To determine the risk that Rozol may pose to black-capped vireos, we conducted a thorough review of their life history to determine to what extent the range, habitat preferences, and diet of this species overlaps with areas where BTPD colonies occur and the likelihood that black-capped vireos would come into direct or indirect exposure with Rozol bait or dead/dying (poisoned) prairie dogs, resulting in adverse effects. Label restrictions that were designed to limit impacts to non-target species were also considered, but some were not heavily weighted due to factors previously discussed.

A habitat separation exists between the black-capped vireos and BTPDs. Black-capped vireos are a lowland dependent species, preferring mixed evergreen/deciduous shrubland. The BTPDs are native to short-grass prairie habitats typical of the southernmost regions of the Great Plains that extend into north Texas. The BTPDs tend to avoid areas of heavy brush and tall grass due to the reduced visibility that these habitats impose. Therefore, habitats used by black-capped vireos do not overlap with the open prairie habitat required by BTPDs.

While black-capped vireos become omnivorous during winter by adding seeds in their diet, they are otherwise exclusively insectivorous. Black-capped vireos do not prey on rodents or small mammals such as BTPDs, so risk of Rozol poisoning directly from diet is reduced. The risk posed to black-capped vireos from secondary poisoning through consumption of insects containing residues of Rozol (i.e., consumption of insects that have come into contact with Rozol grain bait or poisoned BTPDs) is possible but highly unlikely when all factors herein are considered.

The timing of the black-capped vireos' migration and arrival at the nesting grounds is also a factor. The Rozol label restricts applications to the period between October 1 and March 15 which somewhat limits potential exposures to non-target wildlife. Black-capped vireos leave Texas to migrate south for the winter by mid-September, returning in late March the following year, and would therefore be wintering in western Mexico during the majority of the October 1 to March 15 timeframe when Rozol applications are allowed.

Although the range for the black-capped vireo historically was larger than today, current overlap of the range of the black-capped vireo with BTPDs is geographically limited. Likewise, BTPDs historically occurred over most of the western half of Texas but have been extirpated from portions of their former range (Davis and Schmidly 1994). The range for the black-capped vireo today only marginally overlaps with the range for BTPDs, and different habitat requirements preclude the co-existence of these two species in the same location.

We conclude that adverse effects to black-capped vireos from the proposed action are unlikely due to: 1) limited geographic overlap between the current ranges of the black-capped vireo and BTPD; 2) black-capped vireos migrate to Mexico during the time frame in which Rozol application would be permitted; and 3) in the highly unlikely event that black-capped vireos used habitat where Rozol was applied, their dietary requirements would minimize the probability of primary or secondary exposure. No critical habitat for the black-capped vireo has been designated; therefore none will be affected.

CANADA LYNX

The BA describes that direct effects to Canada lynx are expected to occur based on the potential for them to consume prey items that have consumed the chlorophacinone bait. It further describes that growth and reproductive effects cannot be precluded due to the absence of chronic data; however, growth and reproductive effects are not expected because mortality typically occurs as a result of acute exposure. The BA also stated that the range of Canada lynx overlaps with BTPD habitat. Therefore, it was determined in the BA that the use of chlorophacinone to control BTPDs is likely to adversely affect Canada lynx.

Within the action area, Canada lynx may occur in Montana, Wyoming, and Colorado. Upon further analysis, we have determined that the range of Canada lynx has minimal overlap with BTPD habitat. No overlap of Canada lynx habitat with known BTPD colonies occurs in Montana, and no overlap of Canada lynx habitat with known BTPD colonies or potential range occurs in Wyoming. A very minimal amount of overlap of Canada lynx habitat with the BTPD's overall range in Colorado occurs; however, no overlap with mapped BTPD colonies occurs in Colorado.

Canada lynx are dependent on presence of snowshoe hares and the hare's preferred habitat conditions which include dense understories of young trees, shrubs or overhanging boughs that protrude above the snow and mature multistoried stands with conifer boughs touching the snow surface. Snowshoe hares are not found in BTPD habitat. Canada lynx have been observed (via snow tracking) to avoid open habitats (i.e., prairie dog towns) (Koehler 1990, Staples 1995) during daily movements within the home range. Canada Lynx prefer to move through continuous forest using the highest terrain available such as ridges and saddles (Koehler 1990, Staples 1995). While some Canada lynx may move through open habitats at times during transient or dispersal movements, the likelihood of a Canada lynx moving through a BTPD colony is small, and the likelihood that they would move through a black tailed prairie dog colony that is also being treated with Rozol is so unlikely that it is discountable. Therefore, we do not anticipate adverse effects to Canada lynx from the use of Rozol to treat BTPD colonies.

The BA indicates that adverse effects to Canada lynx critical habitat are expected to occur because critical habitat overlaps with the use area or action area (BTPD habitat). Critical habitat for Canada lynx is not designated in Colorado, and critical habitat in Wyoming and Montana does not overlap with BTPD known occurrences and potential range. Therefore, we conclude that the use of Rozol in BTPD colonies would not adversely affect designated critical habitat for Canada lynx.

ESKIMO CURLEW

The EPA determined that the use of Rozol to control BTPDs is likely to adversely affect the Eskimo curlew. This determination was based on likely exposure to Rozol as indicated by the overlapping ranges for the two species and expected direct and indirect effects to the Eskimo curlew associated with exposure. The EPA concluded in the BA that direct effects to Eskimo curlew could occur due to potential for this species to consume terrestrial invertebrate prey items that have consumed Rozol. Additionally, impacts to terrestrial invertebrates from Rozol exposure were expected to indirectly affect Eskimo curlews by depleting their prey base. The EPA also concluded that potential Rozol exposure to Eskimo curlews would be limited to the spring migration and reproductive effects could not be precluded based on an absence of chronic exposure and effects data for any species.

The Eskimo curlew was identified as being threatened by extinction under the Endangered Species Preservation Act of 1966 (FWS 1967) and, after the ESA was enacted in 1970, was listed as endangered (FWS 1970). The species once numbered in the hundreds of thousands, but declined rapidly in the 1870s to 1890s and is now most likely extinct. No nests have been located in 140 years, and the last specimen was obtained in the 1960s (Environment Canada 2007). Environment Canada and the Service have both concluded that recovery of the Eskimo Curlew is currently not considered feasible as there is very little information on locations of habitat necessary for survival or recovery and there are very few, if any, individuals left in existence (Environment Canada 2007, FWS 2011e).

Recent quantitative methods used to evaluate the probability of the Eskimo curlew's existence have estimated extinction dates of 1967 and 1965, respectively, with the upper bounds of 95 percent confidence intervals in 1977 and 1970 (Elphick et al. 2010, FWS 2011e). These estimates are based on the last uncontroversial record of observance, a specimen that was shot in Barbados in 1963 (FWS 2011e). From 1963 to the spring of 2009, 39 potential sightings have occurred in 22 different years (Committee on the Status of Endangered Wildlife in Canada 2009); however, the reliability of these sightings is variable, and none have been confirmed by physical evidence (FWS 2011e). If controversial records of observance are included, then the analysis estimates an extinction date of 2008 with the upper bound of 95 percent confidence interval reaching 2013 (FWS 2011e).

Eskimo curlews were not well studied before their decline; thus, their association with prairie dog towns is largely unknown. The related long-billed curlew (*Numenius americanus*) is associated with BTPD colonies in western South Dakota, but that species also uses short- and mixed-grass prairies absent of prairie dogs (Sharps and Uresk 1990). In Kansas, where the last Eskimo curlew sighting was in 1902, habitat preference purportedly included prairie dog towns where they fed on invertebrates (Kansas Department of Wildlife and Parks 2000). Although there is some indication that prairie dog towns may provide foraging habitat for Eskimo curlews, more relevant habitat factors that have likely contributed to their decline include the wide-scale conversion of grassland to agriculture, fire suppression, and the extinction of the Rocky Mountain grasshopper (*Melanoplus spretus*) as an important food source (FWS 2011e).

In conclusion, Eskimo curlews are likely already extinct or at best extremely rare; thus, direct and indirect effects from Rozol exposure are so highly unlikely to occur as to be considered discountable. Therefore, the Service does not anticipate adverse effects to Eskimo curlew from use of Rozol on BTPDs. No critical habitat for the Eskimo curlew has been designated; therefore none will be affected.

GOLDEN-CHEEKED WARBLER

The golden-cheeked warbler is the only breeding bird endemic to the State of Texas. The golden-cheeked warbler is a small (12 cm or 4.5 in.) migratory songbird whose nesting range is currently confined to habitat in 33 counties in central Texas. Golden-cheeked warblers were federally listed as endangered in 1990. The birds are dependent on Ashe juniper (blueberry juniper or cedar) for fine bark strips used in nest construction. Although nests may be placed in various species of trees, such as Ashe juniper, Texas oak, live oak, and cedar elm, all nests contain strips of Ashe juniper bark woven together with spider webs. Golden-cheeked warblers feed almost entirely on caterpillars, spiders, beetles, and other insects found in foliage. The species winters in southern Mexico and Central America. In the period from July to August, golden-cheeked warblers migrate southward from Texas through the pine-oak woodlands of eastern Mexico and begin returning to Texas in late February. The earliest arrival date on the breeding grounds in Texas is March 2; however, most arrive mid-March (Pulich 1976).

The EPA determined that the golden-cheeked warbler may be adversely affected by Rozol use because the species' range overlaps with that of the BTPD, and they assumed that golden-cheeked warblers could ingest toxic levels of Rozol via consumption of invertebrates exposed to chlorophacinone. For our assessment of the risk that Rozol may pose to golden-cheeked warblers, we reviewed their life history to determine to what extent the range, habitat preferences, and diet of this species overlaps with areas where BTPD colonies occur and the likelihood that golden-cheeked warblers would come into direct or indirect exposure with Rozol bait or poisoned prairie dogs that could result in adverse effects. Label restrictions that were designed to limit impacts to non-target species were also considered, but some requirements were not heavily weighted due to limitations with the label restrictions previously discussed.

Golden-cheeked warblers use juniper and oak dominated woodlands and prefer canyon or hill country. The BTPDs in Texas are native to short-grass prairie habitats typical of the southernmost regions of the Great Plains that extend into north Texas and tend to avoid areas of heavy brush and tall grass due to the reduced visibility that these habitats impose. Therefore, habitats used by golden-cheeked warblers do not overlap with the open prairie habitat used by BTPDs.

Golden-cheeked warblers are exclusively insectivorous. Golden-cheeked warblers do not prey on rodents or small mammals such as BTPDs, so risk of Rozol poisoning directly from diet is not expected. The risk posed to golden-cheeked warblers from secondary poisoning through consumption of insects containing residues of Rozol (i.e., consumption of insects that have come into contact with Rozol grain bait or poisoned BTPDs) is possible but considered unlikely when life histories of both species are considered.

The warbler's migration timing is a factor to consider. The Rozol label restricts applications to the period between October 1 and March 15 which somewhat limits potential exposures to non-target wildlife. Golden-cheeked warblers leave Texas in August, returning in late February the following year and, therefore, would be wintering in Mexico and Central America during the majority of the October 1 to March 15 timeframe when Rozol applications are allowed.

Although the range for the golden-cheeked warbler was historically larger than today, its current overlap with BTPDs is limited geographically. Historically, BTPDs occurred over most of the western half of Texas, but they have been extirpated from portions of their former range (Natural Science Research Laboratory 2012). Although the range for the golden-cheeked warbler marginally overlaps with the range for BTPDs, different habitat requirements preclude the co-existence of this avian species with the BTPD.

We conclude that adverse effects to golden cheeked warblers from the proposed action are unlikely due to: 1) limited geographic overlap between the current ranges of the golden-cheeked warbler and BTPD; 2) in the highly unlikely event that golden-cheeked warblers would use habitat where Rozol was applied, their dietary requirements would minimize the probability of primary or secondary exposure; and 3) golden-cheeked warblers winter in Mexico during the time frame in which Rozol application would be permitted. No critical habitat for the golden-cheeked warbler has been designated; therefore none will be affected.

GULF COAST JAGUARUNDI

The EPA determined that the use of Rozol is likely to adversely affect the Gulf Coast jaguarundi based on potential direct effects from prey that may consume chlorophacinone bait, including BTPDs and non-target animals. However, the BA indicated that there would be no indirect effects from prey-base loss expected because this species' habitat is distinct from BTPD habitat. No map was provided in the BA where the Gulf Coast jaguarundi overlaps with the BTPD, but the Service agrees with the EPA that there is no overlap in range between the two species.

The Gulf Coast jaguarundi is reported from Mexico, southern Arizona, and southern Texas. It is not found within the BTPD range. As such, any effects from the action to the Gulf Coast jaguarundi are considered to be highly unlikely to occur. Therefore, the Service does not anticipate adverse effects to the Gulf Coast jaguarundi from use of Rozol on BTPDs. No critical habitat for the Gulf Coast jaguarondi has been designated; therefore none will be affected.

OCELOT

The EPA determined that the ocelot may be adversely affected by Rozol use based on potential direct effects from prey that may consume chlorophacinone bait, including BTPDs and non-target animals. However, the BA indicated that there would be no indirect effects from prey-base loss expected because this species' habitat is distinct from the BTPD habitat.

The ocelot is found in Mexico, southern Arizona, and southern Texas. There is no overlap between the BTPD and the ocelot; therefore, we conclude that the proposed action is not likely to adversely affect the ocelot. No critical habitat for the ocelot has been designated; therefore none will be affected.

PIPING PLOVER

The action area encompasses the entire United States breeding range of the Northern Great Plains population of the piping plover. Piping plovers have nested near prairie dog towns (within 0.10 mile) (USCOE 2011, Kempema et al. 2009, Montana Natural Heritage Program 2011). However, our analysis suggests that there is little, if any, overlap between prairie dog towns and piping plover critical habitat or known nesting areas. Additionally, piping plovers' predilection to nest and forage in sandy or gravelly areas near water with little vegetation make it unlikely that they would extensively use prairie dog towns. In areas where prairie dog towns are in close proximity to nesting habitat, it is possible that piping plovers could ingest invertebrates that had fed on Rozol or that dying prairie dogs may expire along the shoreline, exposing piping plovers to Rozol through maggots. However, because piping plovers are not expected to forage in the prairie dog towns directly and the Rozol use season ends before piping plovers are likely to encounter prairie dog colonies (see below), the risk of exposure to piping plovers is unlikely.

Piping plover critical habitat has been designated along Lake Oahe in South Dakota. The primary constituent elements on reservoirs are defined as "sparsely vegetated shoreline beaches; peninsulas; islands composed of sand, gravel, or shale; and their interface with the water bodies" (FWS 2002a). Piping plover breeding habitat is by nature ephemeral and cyclical with unvegetated habitat emerging following wet periods, only to become vegetated over time and unsuitable until the next flood inundates the habitat again, clearing it of vegetation. Since prairie dogs use vegetated areas which are not suitable for piping plovers even after the prairie dogs have clipped the grasses in the area, prairie dog towns would not have the primary constituent element of "sparsely vegetated shoreline beaches." Therefore, since Rozol application would occur only in prairie dog towns which do not have the primary constituent elements that define piping plover critical habitat, we do not anticipate impacts.

The Rozol label allows treatment only between October 1 and March 15 of the following year. During this time period, piping plovers would be on the wintering grounds which do not overlap with the BTPD range. Contaminated prairie dog carcasses have been documented on the surface up to 29 days post treatment, so some piping plovers arriving on the breeding grounds in April and May could overlap temporally when contaminated carcasses are available. There is some potential for disturbance by applicators collecting carcasses in April when piping plovers have started to arrive, but this disturbance is expected to be minimal since the activity will be concentrated in the prairie dog towns, which piping plovers do not use for nesting.

A number of documented prairie dog towns occur near the designated critical habitat along the Missouri River and reservoir system in North Dakota and South Dakota. However, no piping plover nests have been documented to occur within the prairie dog towns (USCOE 2011), nor have piping plovers been observed to forage within prairie dog towns (Someson 2012, personal communication). Piping plovers have not been documented to eat grains, so they would be unlikely to feed directly on Rozol. Secondary poisoning is a potential risk if piping plovers were to prey on maggots or other insects that had fed on the bait directly or on contaminated prairie dogs. In the Great Lakes, maggots were postulated to be the source of Type E botulism that infected and killed some piping plovers (FWS 2009e). In the two reported cases where piping plovers have been observed foraging on carcasses, the carcasses have been along the shoreline;

plovers were not documented to leave their traditional foraging areas to forage on carcasses (Keane 2002, FWS 2009e). We do not anticipate Rozol use along the Missouri River shoreline, so exposure of piping plovers to contaminated maggots is not expected.

Piping plovers have been documented to nest up to one-half mile from the water along the reservoirs (Pavelka 2008, personal communication), but this was in low water years and the nests were below the elevation at which the reservoirs are considered full in a normal year. Most nests are initiated relatively close to the water (Anteau et al. 2011). The average number of piping plovers nesting on the Missouri River reservoirs annually from 1994-2010 has been 496 (USCOE 2011), but only a very small subset (less than a few dozen) of these were near prairie dog towns and none were in prairie dog towns.

The risk of secondary poisoning is unlikely due to the chain of events that would have to occur for piping plovers to be exposed. Since piping plovers do not eat grain or carcasses directly, poisoning would have to occur via a secondary route. For terrestrial insects to be available for piping plover forage, contaminated insects would have to leave the prairie dog town and move to unvegetated habitat (most likely along the water's edge) where piping plovers do most of their foraging, and be ingested by piping plovers. It is unlikely that piping plovers would be exposed to sufficient Rozol concentrations in this manner.

In summary, impacts to piping plovers are not anticipated because:

- The Rozol label only allows application to occur between October 1 and March 15 of the following year, when piping plovers are absent from the breeding grounds.

- The potential Rozol exposure routes are circuitous with both possible transmissions being via insects; neither of which is expected to occur.

    - *Route 1 – the invertebrates have eaten the bait directly and then move to piping plover foraging areas.* While this route is possible, the time lag between the last application of Rozol and the arrival of piping plovers reduces the likelihood of impact. Further, prairie dog colonies are generally well removed from piping plover nesting areas, and contaminated invertebrates would have to move from the prairie dog town to piping plover habitat to be exposed to ingestion by piping plovers.

    - *Route 2 - the invertebrates (most likely maggots) may become contaminated through feeding on a contaminated carcass.* This route would require a contaminated carcass from a Rozol application (that had occurred weeks to months earlier) to be located in piping plover foraging habitat on the shoreline, which would be out of the prairie dog town, and remain in place long enough to become infested with maggots. The maggots would have to be carrying a high enough concentration of Rozol to affect piping plovers and/or the piping plovers would have to consume them in sufficient quantity to be impacted.

- Most of the activity associated with poisoning would occur outside of piping plover use areas, so disturbance associated with poisoning activities is unlikely.

- By definition, prairie dog habitat does not have the primary constituent elements that define piping plover critical habitat. Thus, we do not anticipate that Rozol application would adversely affect designated critical habitat.

Based on the above information, the Service concludes that adverse effects to piping plovers from the use of Rozol to poison BTPDs are not likely, and the action is not likely to adversely affect designated critical habitat.

WHOOPING CRANE

In the BA, the EPA concludes that the use of Rozol to control the BTPD is likely to adversely affect the whooping crane for the following reasons:

> *Direct effects to the whooping crane are expected to occur based on the potential for this species to consume the chlorophacinone bait (RQ of 0.89 which exceeds the LOC of 0.1) or other prey items that may have consumed the chlorophacinone bait (RQ of 0.104 for exposure to non-target animals which exceeds the LOC of 0.1). Growth and reproductive effects cannot be precluded due to the absence of chronic data.*
>
> *Indirect effects from the loss of the prey base are expected because effects to individuals within populations have been demonstrated in mammals, birds, and terrestrial invertebrates. No indirect effects from habitat loss are expected because this species does not use BTPD burrows.*
>
> *Habitat modification for the whooping crane is expected because the critical habitat for the whooping crane overlaps with the use area (BTPD habitat).*

The BA map indicates some overlap between the whooping crane and BTPD in Montana, North Dakota, South Dakota, Wyoming, Colorado, Nebraska, Kansas, and Oklahoma. The map does not depict any counties in Texas; the Service has sent a map of Texas counties to the EPA indicating potential whooping crane presence.

Three populations of whooping cranes exist in the wild: 1) the Aransas Wood Buffalo Population, 2) the Florida Population, and 3) the Eastern Migratory Population. The Aransas Wood Buffalo Population nests in the Wood Buffalo National Park in the Northwest Territories of Canada and in Alberta, Canada. This population migrates through eastern Montana, North Dakota, South Dakota, Nebraska, Kansas, Oklahoma, and Texas between breeding grounds in Canada and wintering grounds of Aransas National Wildlife Refuge on the Gulf Coast of Texas. This migration route overlaps with the range of BTPDs. The Florida Population is non-migratory and is located on the Kissimmee Prairie, south of Orlando in Osceola and Polk counties and does not overlap with the range of BTPDs. The Eastern Migratory Population was reintroduced to the Necedah National Wildlife Refuge in Wisconsin with captive birds trained to migrate to Chassahowitzka National Wildlife Refuge on the Gulf Coast of Florida and does not overlap with the range of BTPDs. The Aransas Wood Buffalo Population is the only self-sustaining wild population. The Florida Population and Eastern Migratory Population are introduced and are designated nonessential experimental by the Service.

As noted in the BA, the whooping crane is a territorial nester and returns to the same area each year. Whooping cranes summer in marshes and prairie potholes and winter in coastal marshes and prairies. Eggs are laid from April to mid-May. Incubation lasts for a month. At Wood Buffalo National Park, whooping cranes migrate southward in the fall from mid-September to mid-November to winter at the Aransas National Wildlife Refuge. However, those dates may vary. Ten Aransas Wood Buffalo Population whooping cranes were fitted with Global Positioning System (GPS) platform transmitters and were tracked by the Service and The Crane Trust as they migrated from Wood Buffalo National Park to Aransas National Wildlife Refuge. In 2010, whooping cranes left Wood Buffalo National Park as early as August 20 and continued until October 31. They arrived at Aransas National Wildlife Refuge between October 28 and November 26. Whooping cranes spent most of their time in Saskatchewan followed by North Dakota, South Dakota, Nebraska, Kansas, Oklahoma, and Texas. The whooping cranes made stopovers on 39 private properties and 15 public land sites and varied between rivers (including reservoirs on the Missouri River), lakes, wetlands, and uplands. Upland roost sites consisted of corn fields, fields planted in winter wheat, and a harvested rice field. In spring, the migration begins between March 25 and April 15, and some may not leave Aransas National Wildlife Refuge until May.

Diet during the summer consists of larval and nymphal insects, frogs, rodents, berries, small birds, and minnows. On the wintering grounds at Aransas National Wildlife Refuge, whooping cranes feed primarily on blue crabs, razor clams, and wolfberries. During migration, they forage on agricultural waste grains like barley, wheat, and corn, along with frogs, fish, insects, tubers, and crayfish.

Whooping cranes are likely to be migrating between October 1 and December 1 from Wood Buffalo National Park to Aransas National Wildlife Refuge which is the first half of the Rozol application season. During their spring migration from Aransas National Wildlife Refuge to Wood Buffalo National Park in late March, it is possible that Rozol will have been applied to areas within days prior to their departure and contaminated prairie dog carcasses have been documented on the surface up to 29 days post-treatment. While whooping cranes are not known to use BTPD colonies during their migration between wintering and breeding areas, it is possible to foresee some possible Rozol exposure routes since whooping cranes are known to eat agricultural grains, frogs, fish, insects, tubers, rodents, and crayfish during their migration. Further, since Rozol is grain-based, it could be consumed in amounts that would exceed the RQ for consumption of 0.89 for endangered species. According to the EPA, the whooping cranes would have to eat 23 poisoned mice or more than 1 poisoned BTPD every day for 5 days to reach the LOC. The BA also states that it may be possible for the whooping cranes to consume that many mice in a day but unlikely that it would eat more than one BTPD every day.

Although whooping cranes use a wide range of environments, they primarily depend on highly productive wetlands, marshes, mudflats, wet prairies, rivers, streams, and crop fields for migratory stopover habitat. They feed primarily in a variety of croplands and roost in marshy wetlands or riverine habitats. Heavily vegetated wetlands are not generally used. During migration, whooping cranes are often recorded in riverine habitats such as in the Platte River, North and Middle Loup Rivers, and Niobrara River in Nebraska; the Missouri River in North Dakota and South Dakota; and the Red River in Texas. They roost on submerged sandbars in wide, unobstructed channels that are isolated from human disturbance.

The BTPDs establish colonies near intermittent streams, water impoundments, homestead sites and windmills. However, BTPD colonies are typically in upland locations where the Service has not documented extensive whooping crane use. The greatly reduced vegetative cover in the vicinity of prairie dog colonies may further detract from the possibility of whooping cranes foraging in those areas. Service knowledge of whooping cranes does not suggest that, while foraging, they would venture into prairie dog burrows where Rozol-treated bait is placed. Where both whooping cranes and the BTPD occur, habitat isolation between the whooping cranes and BTPD reduces the chance that the whooping cranes would encounter treated grain.

However, the Service is currently monitoring whooping cranes within the migratory corridor with the use of telemetry data from the current whooping crane tracking study. A relatively small number of whooping cranes are marked with transmitters, but this study may inform whether whooping cranes occur in or near prairie dog colonies. We anticipate that a diagnostic necropsy of any dead whooping cranes will occur and should detect chlorophacinone if that is a factor in their death. If the tracking study or necropsies reveal significant new information or indicate adverse effects are occurring to whooping cranes, we will request that the EPA reinitiate consultation (as per the new information clause in the Reinitiation Notice at the end of the BO). In summary: a) whooping cranes have not been documented to forage or roost in BTPD colonies, b) the occurrence of the species in the proximity of BTPD colonies is not likely to be frequent, c) during migration, whooping cranes are not expected to venture into BTPD colonies, creating a degree of habitat isolation between the two species, and d) mechanisms are in place to further assess whether whooping cranes use BTPD colonies.

There is some potential for whooping crane disturbance by applicators collecting carcasses, but this disturbance is expected to be minimal since the activity will be concentrated in the prairie dog towns which whooping cranes are not known to use. The Service is also unaware of any incidents involving Rozol and whooping cranes despite Rozol's ongoing use as a BTPD rodenticide in the migratory corridor since the early 1990s (Lee et al. 2005).

Whooping crane critical habitat occurs in five sites in four States. They are:

- Cheyenne Bottoms State Waterfowl Management Area and Quivira National Wildlife Refuge in Kansas;
- The Platte River between Lexington and Denman, Nebraska;
- Salt Plains National Wildlife Refuge in Oklahoma; and
- Aransas National Wildlife Refuge and vicinity in Texas.

Each of the five factors normally associated with critical elements pertain to the whooping crane (i.e., space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, or rearing of offspring; and generally, habitats that are protected from disturbances or are representative of the geographical distribution of the listed species).

With exception of the Platte River in Nebraska, all designated critical habitats are Service National Wildlife Refuges or WaterfowlManagement Areas that are unlikely to have Rozol use on their properties; doing so would result in a future Section 7 consultation. The BTPD colonies

are not known to occur in the designated critical habitat areas. Burrows are not specified critical elements of whooping crane critical habitat. The EPA's conceptual impact model on page 60 of the BA lists "altered plant community composition" as a second indirect effect on habitat resulting from BTPD control. Reduction or eradication of BTPD colonies could lead to increases in vegetation height and density at sites treated with Rozol. However, some thicker vegetation is unlikely to cause adverse effects to the critical habitat for species because there are minimal BTPD colonies in whooping crane designated critical habitat.

We conclude that adverse effects to the whooping crane from the proposed action are unlikely. Additionally, we believe that adverse effects to whooping crane critical habitat are unlikely.

C. SPECIES FOR WHICH CONSERVATION MEASURES PRECLUDE ADVERSE EFFECTS

The following species analyses are based on the EPA's adoption of conservation measures that are anticipated to result in the avoidance of adverse effects to federally listed species/critical habitats, primarily by identifying areas where the product is prohibited and/or applying timing restrictions for the application of Rozol. As a result of the conservation measures incorporated into the proposed action by the EPA and the applicant, we conclude that adverse effects are not likely for: 1) the Chiricahua leopard frog, 2) grizzly bear, 3) jaguar, 4) New Mexico ridge-nosed rattlesnake, 5) Mexican spotted owl, and 6) PMJM. Conservation measures were also developed for the black-footed ferret and the gray wolf (Mexican subspecies); see "Species for which Adverse Effects are Anticipated" section of this BO for those species analyses.

CHIRICAHUA LEOPARD FROG

The area of concern for the Chiricahua leopard frog relative to this consultation includes New Mexico, the only State where the range of this species overlaps the use of Rozol as BTPD bait. In New Mexico, the species occurs in Catron, Hidalgo, Grant, Sierra, and Socorro Counties, which is about 16 to 19 percent of its historical localities (FWS 2007b). Fourteen units of critical habitat have been designated in New Mexico for the Chiricahua leopard frog (FWS 2012a). Chiricahua critical habitat and the BTPD range appear to overlap in New Mexico, at least at a landscape-scale level.

The EPA determined that the proposed action may directly affect the Chiricahua leopard frog because the range of the species overlaps with BTPD habitat. Although Catron, Hidalgo, Grant, Sierra, and Socorro Counties do not have large colonies of BTPDs (1,541 acres or 2 percent of Statewide acres), small scattered colonies may occur adjacent to Chiricahua leopard frog habitat, thus creating the possibility that Rozol could be used within or near Chiricahua leopard frog habitats (Johnson et al. 2003). The EPA determined that the Chiricahua leopard frog could be affected by Rozol applications through consumption of poisoned invertebrates that have ingested Rozol or loss of invertebrate prey base. Most likely, we believe such effects would be limited to individual Chiricahua leopard frogs and would not result in large scale die-offs or population losses. In addition, Chiricahua leopard frogs only eat live prey and would not consume a dead organism; they do not scavenge. A large portion of the Chiricahua leopard frog range in New Mexico is located on U.S. Forest Service lands, and agency approval would be required before Rozol could be deployed.

The EPA has agreed to adopt conservation measures as part of their proposed action to minimize potential exposure of Chiricahua leopard frogs to Rozol by precluding its application in Catron, Hidalgo, Grant, Sierra, and Socorro Counties. Because designated critical habitat captures a large portion of the range of Chiricahua leopard frog in New Mexico, the proposed conservation measure of prohibiting Rozol use in Catron, Hidalgo, Grant, Sierra, and Socorro Counties would greatly reduce the potential for exposure to Rozol and significantly reduce the potential for adverse effects to the Chiricahua leopard frog and its proposed critical habitat. Additionally, Rozol would not be applied within critical habitat; thus, no Rozol impacts to critical habitat are anticipated.

Accordingly, implementation of the proposed action and its associated conservation measures is not expected to result in adverse effects to the Chiricahua leopard frog or adverse effects to its designated critical habitat.

GRIZZLY BEAR

In the BA, the EPA describes direct effects to grizzly bears that are expected to occur based on the potential for the species to consume chlorophacinone bait (primary exposure) or other prey items that may have consumed chlorophacinone bait (secondary exposure). The EPA assumed chlorophacinone exposure to grizzly bears would occur because the grizzly bear range overlaps BTPD habitat and the Rozol application season overlaps periods during which grizzly bears are active and not hibernating. The EPA defines the Rozol application period on the label as occurring between October 1 and March 15. The BA further describes that "growth and reproductive effects cannot be precluded due to the absence of chronic data; however, growth and reproductive effects are not expected because mortality typically occurs as a result of acute exposure." The EPA assumes acute exposure apparently based on the assumption that "a grizzly bear is most likely to encounter a Rozol application area shortly before or after hibernation at which time the bear is engorging itself." The EPA calculated RQs that greatly exceeded a 0.1 LOC for grizzly bears (Table 5.3, page 83), especially for primary consumption (RQ = 75.42). The BA also describes the potential indirect effects due to the loss of prey base. Therefore, the EPA concluded in their BA that use of Rozol is likely to adversely affect grizzly bears.

Since the preparation of the BA, the EPA has agreed to impose a timing restriction so use of Rozol would only be used during the grizzly bear denning period (use would only occur between December 1 and March 1) within those counties in Montana where grizzly bears may occur and may overlap with BTPDs (see list below). This measure would greatly reduce the potential for overlap of grizzly bears and Rozol-treated BTPD colonies during the period where grizzly bears could be exposed to Rozol through primary or secondary exposure (the non-denning period). Further, there are very few BTPD colonies that exist in the mountain/prairie transition zone where the occasional grizzly bear may encounter BTPD colonies. Based on a map produced by the Montana Natural Heritage Tracker website, less than 10 known or documented BTPD colonies occur where grizzly bears currently may occur (Montana Natural Heritage Program 2011).

Counties in Montana with Rozol treatment timing restrictions:

- Carbon
- Stillwater, South of I-90
- Sweetgrass, South of I-90
- Park, South of I-90
- Gallatin, South of I-90
- Madison
- Powell
- Lewis and Clark
- Cascade
- Teton
- Pondera
- Glacier
- Toole

With the timing restriction, the likelihood of grizzly bear exposure to chlorophacinone from Rozol use to control BTPDs is low enough to be considered discountable. With few BTPD colonies in areas where grizzly bears are likely to occur, the likelihood of grizzly bears using BTPD habitats as part of their home range is low. The restricted use season for Rozol (December 1 to March 1) would further reduce the likelihood that a grizzly bear will encounter poisoned prairie dogs or unconsumed bait. By December 1, no grizzly bears are expected to be in BTPD habitat as they will have moved to higher elevation mountain slopes to den. On average, grizzly bears emerge from dens in the beginning of April. However, grizzly bears would not be expected to use grassland/prairie habitat, including BTPD, until 2 to 4 weeks after emerging from their dens if they use those areas at all. Therefore, grizzly bears would not be expected to overlap with BTPD colonies for approximately 6 to 8 weeks after March 1 (around 50 days or more post any final application).

With the timing restriction conservation measure, we conclude that adverse effects to grizzly bears from primary exposure to Rozol are highly unlikely to occur. Prevalence of chlorophacinone bait visible in or around burrows declined by approximately 87 percent by day 7 (Lee and Hygnstrom 2007). Thus, after approximately 50 days post-application when grizzly bears may first encounter a Rozol-poisoned BTPD town, essentially all of the bait is likely to have been consumed by BTPDs or non-target species. The EPA calculated that a grizzly bear needs only to consume 4 grams of bait per day for 5 days to exceed a 0.1 LOC (page 99 of the BA), indicating that grizzly bears may not need to eat much Rozol bait to be susceptible to adverse effects. However, after 50 days following application, it is likely that an insufficient amount of bait would remain for grizzly bears to consume. Therefore, based on the timing restriction and the minimal overlap of grizzly bear habitat and BTPD colonies, we conclude that the likelihood of a grizzly bear encountering and consuming a sufficient quantity of Rozol bait to result in harmful effects is so low that it is discountable.

The likelihood of detrimental effects to grizzly bears from secondary exposure to Rozol is also so low that it is discountable. The die-off of BTPDs and non-target animals following a Rozol application would likely reach its conclusion before a grizzly bear would encounter a poisoned colony. Fifty or more days following application, few, if any, Rozol-poisoned carcasses or prey debilitated by exposure to Rozol would be available for consumption by grizzly bears. While moribund BTPDs were detected by 29 days after Rozol application (Vyas 2010a), the prairie dog availability is not expected to be high 50 days following application. Most prairie dogs are expected to die within days to weeks of application, and predators and scavengers would likely remove most prairie dogs by the time grizzly bears may encounter Rozol-poisoned colonies.

Therefore, by the time grizzly bears may use habitat within these areas, the Services concludes there will be insufficient quantities of available prey items or bait to cause adverse effects.

It is also the Service's conclusion that indirect effects to grizzly bears due to the loss of prey base from use of Rozol are insignificant. Few BTPD colonies occur in areas where grizzly bears also occur, and prairie dogs are not a significant dietary item for grizzly bears.

In summary, few BTPD colonies occur in areas accessed by grizzly bears and, with the restricted timing of Rozol use in grizzly bear areas (between December 1 and March 1), the Service does not anticipate adverse effects to grizzly bears as a result of Rozol use on BTPDs in those areas. No critical habitat for the grizzly bear has been designated; therefore none will be affected.

JAGUAR

The EPA determined that the registration and use of Rozol may affect and is likely to adversely affect the jaguar based on potential direct effects from prey that may consume chlorophacinone bait, including BTPDs and non-target animals. In addition, the EPA's BA indicates that there could be indirect effects from prey-base loss.

The jaguar is reported from Mexico, Arizona, and New Mexico. It is rarely found (one report in the last 20 years) within the action area in the Peloncillo Mountains of Hidalgo County, New Mexico, near the Arizona border. Jaguars are generalist predators typically foraging on diurnal mammals (Seymour 1989). The jaguar is a wide-ranging species that might occasionally encounter prairie dogs; however, there are few BTPDs in Hidalgo County (Johnson et al. 2003). The proposed conservation measure of prohibiting Rozol application in Hidalgo County substantially reduces the risk of Rozol exposure to the jaguar. Based on the low BTPD abundance, unlikely interaction of the jaguar and BTPD, and prohibition of Rozol application in the area occupied by the jaguar, the Service does not anticipate adverse effects to the jaguar. No critical habitat for the jaguar has been designated; therefore none will be affected.

MEXICAN SPOTTED OWL

The EPA determined that the proposed action may directly affect the Mexican spotted owl because the range of the species overlaps with BTPD habitat at a large landscape scale. The EPA determined that the Mexican spotted owl could be affected by application of Rozol through consumption of poisoned prey or loss of prey base, and adverse effects to Mexican spotted owl critical habitat may occur.

Within the action area for this project, the Mexican spotted owl occurs within Colorado, New Mexico, and western Texas. In Texas, the Mexican spotted owl is only known from the Guadalupe Mountains National Park (FWS 1995). The action area was analyzed for possible effects to the Mexican spotted owl that include the BTPD range within the three States listed. Effects may extend beyond the use area due to exposure to individuals or via prey items with chlorophacinone residues if found outside of their described range. The final Mexican spotted owl critical habitat rule (FWS 2004) designated approximately 3.5 million ha (8.6 million acres) of critical habitat in Arizona, Colorado, New Mexico, and Utah, mostly on Federal lands (FWS

2004). Within this larger area, critical habitat is limited to areas that contain the primary constituent elements (FWS 2004). The primary constituent elements include forest structure for nesting and prey maintenance but not the prey base itself (FWS 2004). In summary:

- Known habitat use by the Mexican spotted owl does not correspond with BTPD habitat; thus, the Mexican spot owl is considered extremely unlikely to occur within BTPD habitats where Rozol will be applied. The potential for Mexican spotted owls to experience secondary exposure to chlorophacinone is considered so unlikely as to be discountable.

- The proposed action will not result in any effects to the PCEs of designated critical habitat for the Mexican spotted owl. PCEs for the Mexican spotted owl include mixed-conifer, pine-oak, and riparian forest types that provide for one or more of the owl's habitat needs for nesting, roosting, foraging, and dispersing. These PCEs do not correspond with BTPD habitat and are unlikely to occur within the areas ROZOL is applied. Therefore, the potential for Mexican spotted owl PCEs to be adversely affected by chlorophacinone is considered so unlikely as to be discountable.

- The prohibition of Rozol application in Catron, Grant, Sierra, and Socorro Counties protect important Mexican spotted owl ecological management units and designated critical habitat.

Based on the above, the Service anticipates that adverse effects to Mexican spotted owls or their critical habitat are highly unlikely to occur.

NEW MEXICO RIDGE-NOSED RATTLESNAKE

The BA indicates that New Mexico ridge-nosed rattlesnakes are unlikely to be killed by bait ingestion because the RQ is less than the LOC, but direct effects based on reproduction cannot be precluded. Additionally, indirect effects from prey-base loss are expected because effects to potential prey species have been demonstrated. No indirect effects from habitat loss are expected because this species does not use BTPD burrows. In addition, the BA indicates that adverse effects to designated critical habitat are expected because of overlap with BTPD habitat.

The New Mexico ridge-nosed rattlesnake is reported from Mexico, Arizona, and New Mexico. Within the action area, the New Mexico ridge-nosed rattlesnake is only found in Hidalgo County, New Mexico. New Mexico ridge-nosed rattlesnakes are found in steep, rocky canyons with intermittent streams and on talus slopes in the Animas Mountains. The BTPD habitat does not overlap with the New Mexico ridge-nosed rattlesnake, although occasional prairie dogs might be found in adjacent habitats where the action might indirectly affect the species. The EPA adopted the conservation measure of excluding Hidalgo County from the area where Rozol may be applied, substantially reducing the potential impacts of the action to the New Mexico ridge-nosed rattlesnake. Because of the low BTPD abundance in Hidalgo County (Johnson et al. 2003), the low probability of interaction between the New Mexico ridge-nosed rattlesnake and BTPD, based on differing habitat use of each species, and Rozol use prohibition in the area occupied by the Mexico ridge-nosed rattlesnake, effects from the action are unlikely to occur. The Service does not anticipate adverse effects to the New Mexico ridge-nosed rattlesnake.

Designated critical habitat for the New Mexico ridge-nosed rattlesnake occurs only in Hidalgo County within the action area. There are no known BTPDs in designated critical habitat. The conservation measure of excluding Rozol application in Hidalgo County precludes effects of the action on designated critical habitat. Thus, adverse effects to New Mexico ridge-nosed rattlesnake designated critical habitat are not anticipated.

PREBLE'S MEADOW JUMPING MOUSE

In the BA (page 104), the EPA concludes that the use of Rozol to control the BTPD is likely to adversely affect the PMJM (*Zapus hudsonius preblei*) for the following reasons:

> *The range of this species overlaps with Black-tailed prairie dog habitat. Rozol Prairie Dog bait application season for the control for Black-tailed prairie dogs overlaps periods during which the Preble's meadow jumping mouse is active and not hibernating. However, Preble's meadow jumping mice will be hibernating during most of this time. Chlorophacinone can be applied between October 1 and March 15 or spring green-up, whichever occurs later. Preble's meadow jumping mice typically enter hibernation between late August and October and come out of hibernation in May. Based on the life history information it seems reasonable that the Preble's meadow jumping mouse could be exposed to the chlorophacinone bait. A Preble's meadow jumping mouse would have to eat less than one grain of Rozol Prairie Dog bait per day for five days to reach the LOC. It is possible that a Preble's meadow jumping mouse could consume this amount of bait. The Preble's meadow jumping mouse is most likely to encounter a Rozol application area shortly before or after hibernation at which time the mouse is engorging itself. This only increases the likelihood that the bait would be consumed.*

The PMJM is found in Wyoming and Colorado, in both the North Platte River and South Platte River basins, from the eastern flank of the Laramie Mountains and the Laramie Plains in southeastern Wyoming south along the eastern flank of the Front Range in Colorado and into the headwaters of the Arkansas River Basin near Colorado Springs, Colorado. The EPA map for this consultation, indicating the overlap of the initial area of concern with the PMJM range, erroneously shows that range to be throughout all of Wyoming (the EPA made note of this error and committed to correcting it for future analyses).

The action area defined by the EPA in the BA broadly overlaps the range of the PMJM. However, the known distribution of the PMJM and the known distribution of the BTPD within Wyoming and Colorado overlap significantly less than depicted in the BA. This inaccuracy results from the inclusion of areas in the mapped PMJM range where potential habitat may exist but where the PMJM is not known to occur and from the EPA's defined action area in Wyoming and Colorado extending well beyond the actual range of the BTPD.

In Wyoming, the PMJM is known to occur only in Albany, southern Converse, Laramie, and Platte counties. The PMJM is not thought to occur in Wyoming's Goshen and Niobrara Counties to the east or eastern Laramie County (Keinath 2001). Occurrence of the PMJM and BTPD in

Wyoming overlaps primarily in portions of southern Converse County and western Platte County (Wyoming Natural Diversity Database [WYNDD] 2011). Known distribution of the PMJM in Colorado includes Boulder, Douglas, El Paso, Elbert, Jefferson, Larimer, and Weld Counties. The easternmost captures extend to western Weld County, western Elbert County, and north-central El Paso County. No recent captures of the PMJM have been documented within its potential range in Adams, Arapahoe, Broomfield, Denver, or Morgan Counties, and it is likely that the PMJM does not occur in these areas. Occurrence of the PMJM and BTPD in Colorado overlaps primarily in west-central Weld County, eastern Boulder County, parts of Jefferson County, western Elbert County, eastern Douglas County, and northern El Paso County (Colorado Division of Parks and Wildlife (CPW) 2011).

Less than 30 percent of the PMJM distribution is estimated to fall within the range of the BTPD. Within the BTPD range, the species' colonies occupy only a small percentage of the area, just over 1 percent in Wyoming (Grenier et al. 2007, WYNDD 2011) and about 3 percent in Colorado (Odell et al. 2008, CPW 2011). While these same percentages may not apply directly to areas of PMJM occurrence, it is reasonable to believe that presence of the PMJM in close proximity to BTPD colonies is infrequent throughout occupied PMJM range.

In the BA (page 32), the EPA states:

> *For the animal species ingestion is the only significant route of exposure and the only exposure route assessed in this document and for that, the species' diet must be that of a granivore or it must be attracted to grain baits to have primary exposure to chlorophacinone; it must be a carnivore or scavenger to have secondary exposure to chlorophacinone. It was also determined that insects may be exposed to the grain bait and may retain residues that are high enough to cause direct mortality to invertivores.*

Preble's meadow jumping mice are omnivores and consume such foods as seeds, fruits, fungi, and insects. Studies specific to the PMJM diet are limited, but fecal analyses suggest that PMJM diet shifts seasonally; it consists primarily of insects and fungus after emerging from hibernation, shifts to fungus, moss, and pollen during mid-summer (July to August), with insects again added in September (Shenk and Sivert 1999). The PMJM would probably consume both treated grain bait and exposed insects if they were encountered.

Where both PMJM and the BTPD occur, habitat isolation between the PMJM and BTPD reduces the chance that the PMJM would encounter treated grain or exposed insects. Typical habitat for the PMJM is comprised of well-developed plains riparian vegetation with adjacent, relatively undisturbed grassland communities and a nearby water source. Well-developed plains riparian vegetation typically includes a dense combination of grasses, forbs, and shrubs; a taller shrub and tree canopy may be present (Bakeman 1997). Areas of highest use by the PMJM tend to be along creeks, and in areas with a high percent cover of shrubs (especially wetland shrubs) and grasses (Trainor *et al.* 2007). In contrast, BTPD colonies are typically in uplands, where their activities greatly reduce vegetative cover in the vicinity of their burrows. The PMJM infrequently enters areas of low, sparse vegetation characteristic of prairie dog colonies. Individual prairie dog burrows in proximity to dense riparian vegetation are most likely to be encountered by the PMJM.

The PMJM is a true hibernator, usually entering underground hibernacula (hibernation nests) in September or October and emerging the following May after a potential hibernation period of 7 or 8 months. The only direct overlap between the PMJM active season and the Rozol treatment period, as reflected in label instructions (October 1 C March 15) is October, when some PMJM remain actively foraging above ground. During the consultation process, Liphatech and the EPA agreed to timing restrictions on Rozol applications, limiting its use within the known range of PMJM occurrence in Wyoming and Colorado to the period November 1 C March 15. Timing restrictions will be included in County Bulletins via the EPA's *Bulletins Live!* for those counties included.

By November 1, all PMJM individuals have likely entered hibernation, and the conservation measure agreed to above would eliminate the likelihood of the species encountering Rozol-treated bait in the fall. Emergence of the mouse from hibernation in spring has not been documented prior to the first week in May. Assuming that the earliest date could be May 1, emergence would follow the last Rozol application by a minimum of 46 days. The majority of individuals are likely to emerge later in May, providing even more temporal separation between the final Rozol application and the PMJM active season. Further, data on the diet of the PMJM indicates that insects and fungus may be preferred rather than seeds when emerging from hibernation (Shenk and Sivert 1999).

In accordance with label instructions, Rozol-treated bait is placed at least 6 inches down BTPD burrows. Our knowledge of the PMJM does not suggest that, while foraging, they would venture into prairie dog burrows where Rozol-treated bait is placed. Spillage, improper baiting, or BTPD digging activity could result in some bait exposed on the ground surface. By the time PMJM emerge from hibernation, bait consumption by various granivores, including insects, would reduce remaining bait availability.

The scenario of the PMJM emerging from hibernation in locations adjacent to BTPD colonies, foraging in those colonies, and encountering and consuming Rozol-treated bait or exposed insects is considered highly unlikely to occur and therefore discountable.

Potential reduction of invertebrates in Rozol-treated areas and its possible effect on PMJM food resources was noted in the EPA's "Effects Determination" within the BA as a possible secondary impact to the PMJM. As stated above, the species feeds on a variety of items, including insects. However, it is unlikely to regularly forage in BTPD colonies, and invertebrate prey from such habitat is not known to be a significant food source for the PMJM. The potential for the PMJM to be adversely impacted by reduction of the invertebrate populations within BTPD colonies appears insignificant.

In summary, occurrence of the PMJM in the proximity of BTPD colonies is likely infrequent within PMJM range. Where it occurs, the PMJM would rarely venture into BTPD colonies, creating a degree of habitat isolation between the two species. The PMJM hibernates November-April, throughout the period of Rozol application as modified by the agreed upon conservation measures (November-March 15), creating a temporal isolation between availability of Rozol-treated bait or affected insects and the PMJM active season. Therefore, the Service does not anticipate adverse effects as a result of the proposed action.

Regarding potential impacts to PMJM critical habitat, in the BA (page 22), the EPA states:

> *Habitat modification for the Preble's meadow jumping mouse is expected because the critical habitat for the Preble's meadow jumping mouse overlaps with the use area (BTPD habitat).*

An estimated 10,200 acres of PMJM critical habitat in Colorado overlaps with the BTPD range, which is approximately 35 percent of all PMJM designated critical habitat. For the PMJM, primary constituent elements (PCEs) of critical habitat are:

- Riparian corridors: formed and maintained by normal, dynamic, geomorphological, and hydrological processes that create and maintain river and stream channels, floodplains, and floodplain benches and that promote patterns of vegetation favorable to the PMJM; containing dense, riparian vegetation consisting of grasses, forbs, or shrubs, or any combination thereof, in areas along rivers and streams that normally provide open water through the PMJM active season; and including specific movement corridors that provide connectivity between and within populations. This may include river and stream reaches with minimal vegetative cover or that are armored for erosion control; travel ways beneath bridges, through culverts, along canals and ditches; and other areas that have experienced substantial human alteration or disturbance.

- Additional adjacent floodplain and upland habitat with limited human disturbance (including hayed fields, grazed pasture, other agricultural lands that are not plowed or disked regularly, areas that have been restored after past aggregate extraction, areas supporting recreational trails, and urban–wildland interfaces).

While the use of Rozol to control the BTPD and subsequent loss of prairie dog colonies is unlikely to adversely impact the PCEs of PMJM critical habitat above, it could have indirect effects to PMJM critical habitat due to the loss of BTPD burrows and cessation of BTPD activities that would otherwise modify vegetation. In the BA (pages 84-85), the EPA states that loss of burrows is not expected to have an adverse impact to the PMJM.

The Service agrees. Burrows of other animals are not specified PCEs of PMJM critical habitat. Since the PMJM digs its own burrows and is not known to be dependent on burrows of other animals, it is unlikely that the PMJM critical habitat would be adversely affected by the loss of prairie dog burrows following Rozol application. In the BA (page 60), the EPA's conceptual impact model lists "altered plant community composition" as a second indirect effect on habitat resulting from BTPD control. Reduction or eradication of BTPDs would likely lead to vegetation of greater height and density at sites of their former BTPD colonies. Where BTPD colonies are abandoned within designated critical habitat or adjacent to other riparian corridors occupied by the PMJM, the altered plant community could be of greater habitat value to the PMJM than low, sparse vegetation typically found within an active BTPD colony.

The Service initially concurred with the EPA's determination that the use of Rozol to control the BTPD may adversely affect the PMJM. However, with the conservation measures agreed to by the EPA and Liphatech as well as further analysis, adverse effects to the PMJM are considered so unlikely as to be discountable. The Service does not anticipate adverse effects to the PMJM or its critical habitat.

D. SPECIES FOR WHICH ADVERSE EFFECTS ARE ANTICIPATED WITH OR WITHOUT CONSERVATION MEASURES

For those species for which conservation measures did not preclude adverse effects, the full analysis of a biological opinion is necessary. Three species are anticipated to experience adverse effects, with or without the conservation measures adopted by the EPA: 1) black-footed ferret, 2) gray wolf and 3) northern aplomado falcon.

BLACK-FOOTED FERRET

a. Status of the Species/Critical Habitat

The black-footed ferret was listed as endangered in 1967 and again in 1970 under early endangered species legislation and was "grandfathered" into the current ESA in 1973 (FWS 2008b). Critical habitat has not been designated for this species. The species' historical range includes 12 States (Arizona, Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, Utah, and Wyoming) and the Canadian provinces of Alberta and Saskatchewan (Anderson et al. 1986).

The black-footed ferret was considered extinct or nearly extinct when a small population was located in Mellette County, South Dakota, in 1964 (Henderson et al. 1969). The last wild black-footed ferret observed at the Mellette County site was in 1974 (Clark 1989). Attempts at captive breeding of a few captured animals from the Mellette County population failed, and when the last captive animal died at Patuxent Wildlife Research Center in Laurel, Maryland, in 1979, the black-footed ferret was again presumed extinct (FWS 1988).

In 1981, a second population was discovered in Meeteetse, Wyoming (Clark et al. 1986, Lockhart et al. 2006). Following disease outbreaks at Meeteetse, all surviving wild black-footed ferrets (totaling 18 individuals) were removed from the wild between 1985 and 1987 to initiate a captive breeding program (FWS 1988). Seven of the black-footed ferrets captured at Meeteetse successfully reared young, leading to a lineage of continuing captive reproduction that provides black-footed ferrets to reintroduction sites today (Hutchins et al. 1996, Garelle et al. 2006). Reintroductions began in 1991 (Table 2) and all extant populations, both captive and reintroduced, descend from these seven "founder" animals (Garelle et al. 2006).

No wild populations of black-footed ferrets have been found since the capture of the last Meeteetse black-footed ferret, despite extensive and intensive range-wide searches. It is unlikely that any undiscovered wild populations remain (Lockhart et al. 2006). No known extant wild populations of black-footed ferrets exist, except those at reintroduction sites.

(1) Ferret Reintroductions

Section 10(j) of the ESA allows reintroduced populations to be designated Nonessential Experimental Populations (NEPs) to ease concerns about listed species reintroductions and facilitate species recovery efforts. To date, 11 black-footed ferret reintroductions have occurred through use of Section 10(j) designated NEP areas in the United States (FWS 2008b). There have also been six black-footed ferret reintroductions in the United States that used Section 10(a)(1)(A) recovery permits. Additionally, there have been black-footed ferret reintroductions in Chihuahua, Mexico, and in Saskatchewan, Canada, in compliance with those countries' statutes, for a total of 19 reintroduction attempts (FWS 2008b, Fargey 2010). See Table 3 for the location and date of initiation of each of the black-footed ferret reintroduction sites.

Table 3. Black-footed ferret reintroductions in North America locations, year initiated, and prairie dog species.

SITE (YEAR INITIATED)	PRAIRIE DOG SPECIES
Shirley Basin, Wyoming (1991)	White-tailed
UL Bend National Wildlife Refuge, Montana (1994)	Black-tailed
Badlands National Park, South Dakota (1994)	Black-tailed
Aubrey Valley, Arizona (1996)	Gunnison's
Conata Basin, South Dakota (1996)	Black-tailed
Ft. Belknap Indian Reservation, Montana (1997)	Black-tailed
Coyote Basin, Utah (1999)	White-tailed
Cheyenne River Indian Reservation, South Dakota (2000)	Black-tailed
Bureau Land Management 40-complex, Montana (2001)	Black-tailed
Wolf Creek, Colorado (2001)	White-tailed
Janos, Mexico (2001)	Black-tailed
Rosebud Indian Reservation, South Dakota (2004)	Black-tailed
Lower Brule Indian Reservation, South Dakota (2006)	Black-tailed
Wind Cave National Park, South Dakota (2007)	Black-tailed
Espee Ranch, Arizona (2007)	Gunnison's
Smoky Valley, Kansas (2007)	Black-tailed
Northern Cheyenne Indian Reservation, Montana (2008)	Black-tailed
Vermejo Park Ranch, New Mexico (2008)	Black-tailed
Grassland National Park, Canada (2009)	Black-tailed

(2) Life History

The black-footed ferret is a medium-sized mustelid typically weighing 1.4 to 2.5 pounds (lbs) (645 to 1,125 grams) and measuring 19 to 24 inches (479 to 600 millimeters) in total length. Upper body parts are yellowish buff, occasionally whitish; feet and tail tip are black; and a black "mask" occurs across the eyes. It is the only ferret species native to the Americas (there are no recognized subspecies). Other ferret species in the genus include the Siberian polecat (*Mustela eversmanni*) and the European ferret (*Mustela putorius*) (Hillman and Clark 1980, Anderson

et al. 1986). The black-footed ferret was first formally described in 1851 by J.J. Audubon and J. Bachman (Clark et al. 1986). The black-footed ferret is endemic to North America. Ferrets entered North America from Siberia approximately 1 to 2 million years ago, spread across Beringia, and advanced southward through ice-free corridors to the Great Plains approximately 800,000 years ago (Wisely 2006). Contrary to early characterizations that addressed natural history, the species was probably common historically, although its secretive habits (nocturnal and often underground) made it difficult to observe (Forrest et al. 1985, Anderson et al. 1986, Clark 1989).

Black-footed ferrets prey primarily on prairie dogs (*Cynomys* spp.) and use their burrows for shelter and denning (Henderson et al. 1969, Hillman and Linder 1973, Forrest et al. 1985). Since black-footed ferrets depend almost exclusively on prairie dogs for food and shelter, and the species' range overlaps that of certain prairie dog species (Anderson et al. 1986) with no documentation of black-footed ferrets breeding outside of prairie dog colonies, the Service believes that black-footed ferrets were historically endemic to the range of three prairie dog species. There are records of black-footed ferrets from the ranges of the BTPD (*Cynomys ludovicianus*), white-tailed prairie dog (*Cynomys leucurus*), and Gunnison's prairie dog (*Cynomys gunnisoni*) (Anderson et al. 1986) which collectively occupied approximately 100 million ac (40 million ha) of intermontane and prairie grasslands (Biggins et al. 1997, Clark et al. 1986, Ernst et al. 2006). Ernst (2008, pers. comm.) estimates that in the United States, this occupied habitat existed within an estimated 562 million ac (228 million ha) of potential habitat. Ernst (2008, pers. comm.) used a geographic information system database to predict the distribution of prairie dog habitat across the United States and concluded that, historically, 85 percent of all black-footed ferrets probably occurred in BTPD habitat, 8 percent in Gunnison's prairie dog habitat and 7 percent in white-tailed prairie dog habitat. We conclude that most black-footed ferrets likely occurred in BTPD habitat.

The black-footed ferret breeds at 1 year of age, from mid-March through early April, and gestation is about 42-45 days. Litter sizes average about 3.5 (Wilson and Ruff 1999). Juveniles disperse in late summer/early fall. The black-footed ferret leads a solitary existence except for the period when mother and young are together (Forrest et al. 1985). It is a "searcher" predator that is generally nocturnal, appearing above ground at irregular intervals and for irregular durations (Clark et al. 1986).

The black-footed ferret's close association with prairie dogs was an important factor in its decline. From the late 1800s to approximately 1960, both prairie dog habitat and numbers were dramatically reduced by the sequential and overlapping effects of habitat loss from conversion of native prairie to cropland, poisoning, and habitat modification due to disease (FWS 2008b). The North American black-footed ferret population declined precipitously as a result (Biggins 2006), and the species was one of the original species listed under early versions of the ESA and was grandfathered in as an endangered species with passages of the ESA in 1973 (FWS 2008b). Black-footed ferret populations in the BTPD range and other prairie dog species are known to exist today only in areas where black-footed ferret reintroductions have occurred (FWS 2008b).

a. Environmental Baseline

Since the 1960s, occupied BTPD acreage has increased from approximately 365,000 acres to approximately 2.4 million acres within the 10 states where Rozol is currently allowed or proposed to be used as a rodenticide (EPA 2010b, FWS 2009b). There is an extensive history of prairie dog poisoning in these 10 states, and we believe that BTPDs are likely to be poisoned by various rodenticides into the future regardless if Rozol is available or not. Current BTPD populations do not indicate a downward trend even though Rozol has been used under SLN labels for BTPD control since 2004 and as early as 1991 under a pocket gopher formulation (Lee et al. 2005, FWS 2009b).

While current information suggests that the BTPD can withstand the impact of Rozol use, prairie dog poisoning is a high magnitude threat to the black-footed ferret (FWS 2008b). Therefore, the conservation measure that prevents Rozol use in black-footed ferret reintroduction areas is key to maintaining the current reintroduction sites and providing a mechanism to accommodate future reintroduction sites.

Nineteen black-footed ferret reintroductions (Table 2) have been undertaken in North America beginning in 1991, and most of these sites continue to have some black-footed ferrets remaining (FWS 2008b, Fargey 2010). Thirteen reintroductions are within the range of BTPDs, and 11 of those sites are within the 10 states where Rozol is either labeled for use or proposed to be used as a prairie dog rodenticide (EPA 2010b). Despite these 19 black-footed ferret reintroductions to date, insufficient time has passed at approximately one third of the sites to indicate whether the existing reintroduction sites may eventually meet criteria for Black-footed Ferret Recovery Plan objectives (FWS 2008b).

A recent estimate of black-footed ferret populations at reintroduction sites indicates approximately 840 black-footed ferrets alive in the wild with approximately half of those located in the BTPD range (FWS 2008b). Since that time, plague has reduced black-footed ferret numbers at the Conata Basin in South Dakota (Griebel 2010) while existing black-footed ferret populations are believed to have expanded in Arizona and Wyoming (Corcoran 2012, Grenier 2008). The Service believes that approximately 800 black-footed ferrets alive in the fall of 2011 is a reasonable estimate of the species' current population numbers in the wild.

To date, there have been a few instances where black-footed ferrets are known to have left a reintroduction site and been located on adjacent property. If a black-footed ferret does disperse from a reintroduction site, there are provisions in the reintroduction site permit or the reintroduction plans to relocate that individual at the request of the adjacent property owner if the owner grants access and permission to do so. This accommodation, while available to adjacent landowners, has rarely been used or needed. The Service does not expect that to change with Rozol use as a BTPD rodenticide.

Landowners adjacent to current black-footed ferret reintroduction sites are not required to conduct surveys for the species prior to undertaking normal ranching operations, such as the use of rodenticides to control prairie dogs. The Service anticipates that future black-footed ferret reintroduction sites will similarly not require black-footed ferret surveys on adjacent properties.

Black-footed ferret surveys can be time consuming and expensive to undertake; requiring them of adjacent landowners prior to normal ranching operations would undermine support for the reintroduction effort.

The Black-footed Ferret Recovery Plan identifies recovery objectives for downlisting the species from endangered to threatened status. The objectives include increasing the captive population of black-footed ferrets to 200 breeding adults and establishing at least 1,500 free ranging breeding adult black-footed ferrets that are distributed between at least 10 populations with no fewer than 30 breeding adults in a population, and those populations shall have the widest possible distribution (FWS 1988). The first objective of increasing the captive black-footed ferret population has been surpassed. The second objective is approximately 25 percent met when fall black-footed ferret numbers of approximately 800 animals are estimated to result in 400 breeding adults by spring, and four reintroductions sites have successfully established free ranging populations and meet recovery objectives (FWS 2008b). This indicates that additional successful black-footed ferret reintroduction sites are needed to meet the downlisting objective. Recovery objectives for complete delisting of the black-footed ferret have not been finalized but are anticipated to include at least 3,000 free ranging breeding adult black-footed ferrets distributed between at least 30 populations. The downlisting objectives indicate that there will need to be significant continued efforts to establish free ranging black-footed ferret populations through the use of reintroductions, and complete delisting of the species will require considerably more reintroductions.

b. Effects of the Action

Rodenticides used to poison prairie dogs can have multiple effects to black-footed ferrets by secondarily poisoning individuals or by destroying the habitat where the species lives or could live. A study in the 1980s evaluated the potential secondary poisoning of chlorophacinone, the active ingredient in Rozol, and found that 5 of 6 domestic ferrets were killed when each domestic ferret was fed 4 poisoned BTPDs over 8 days. The study concluded that chlorophacinone may not be an acceptable prairie dog toxicant based on high secondary toxicity to non-target animals (Fisher and Timm 1987). The Service believes that black-footed ferrets would be similarly killed as the domestic ferrets were, if they consumed prairie dogs poisoned by Rozol. Accordingly, the EPA, Liphatech and the Service developed conservation measures that would prevent Rozol use at current and future black-footed ferret reintroduction sites. These measures were intended to address the secondary poisoning of black-footed ferrets and the loss of prey base for black-footed ferrets at reintroduction sites (EPA 2011c). The issue of black-footed ferret dispersal away from a reintroduction site that might encounter a Rozol poisoned BTPD colony was more difficult to address.

The key challenge with development of the black-footed ferret conservation measures was to ensure that Rozol use would not occur at locations where the species is being reestablished while at the same time ensure that adjacent landowners' ability to manage prairie dogs on their properties would not be impacted. There was discussion about banning Rozol use in areas surrounding black-footed ferret reintroduction sites (up to a county in size), but it was concluded that doing so would increase animosity toward black-footed ferret reintroduction efforts and undermine or prevent reintroductions altogether. Accordingly, to avoid creating that backlash,

conservation measures were developed that would restrict Rozol use at reintroduction sites, but not impose restrictions on adjacent landowners' use of legal rodenticides. As indicated above, the Service does not believe that black-footed ferret surveys on properties adjacent to or in the vicinity of a reintroduction site are needed prior to undertaking otherwise legal activities such as rodenticide use on prairie dogs, and the cost and inconvenience of black-footed ferret surveys on adjacent lands would generate opposition to, and possibly compromise, the black-footed ferret reintroduction effort. If a black-footed ferret disperses from a reintroduction site, and if the landowner wants the ferret relocated and grants permission to access the property, then the relocation can be done under existing mechanisms.

The black-footed ferret conservation measures rely upon identification of existing and future black-footed ferret reintroduction sites on the *Bulletins Live!* database maintained by the EPA and referenced on the Rozol label which becomes part of the legal requirement for label compliance. Prior to Rozol use, applicators are required to consult this database to ensure that they are not applying Rozol at an existing black-footed ferret reintroduction site. If additional reintroductions are started in the future, we will provide the information for those sites to the EPA for inclusion in the EPA's *Bulletins Live!* database to reflect the new black-footed ferret reintroduction sites. The process to add areas to the *Bulletins Live!* database takes approximately 8 months to complete and that timeframe will be factored into the timing of adding new reintroduction sites or modifications to that database.

The Service recognizes that if a black-footed ferret leaves a reintroduction site it could encounter prairie dog colonies where Rozol is being used and could consume poisoned prairie dogs and perish. That mortality must be balanced with the intent of the reintroduction, which is to establish a breeding black-footed ferret population at the reintroduction site. The deaths of black-footed ferrets that leave the reintroduction site are not anticipated to materially affect the reintroduction site's ability to meet recovery objectives for the species because the sites are reliant upon the amount of black-footed ferret habitat within their boundaries to meet those objectives. The Service selects reintroduction sites that have the attributes (i.e., prairie dog acreage, densities, locations, partnerships, etc.) to help meet the black-footed ferret recovery objectives of establishing widely distributed breeding populations. The Service and our reintroduction partners have long understood that dispersing black-footed ferrets from a reintroduction site could be lost from many factors and that use of legal rodenticides off the reintroduction site is one of those factors (FWS 1988, 1994b). Accordingly, we believe that the conservation measure to restrict Rozol use at the reintroduction site, but not on adjacent properties is appropriate.

Another possible effect of Rozol use for BTPD control involves the elimination of possible black-footed ferret reintroduction habitat because of Rozol use. In 2009, the Service estimated that there were approximately 2.4 million acres of BTPDs in the 10 States where Rozol is used or proposed for use as a BTPD rodenticide (FWS 2009b, EPA 2010b). Luce (2006) examined opportunities for immediate and near term potential reintroduction sites and concluded that there are over 70 potential sites within the black-footed ferret range, most of which are in BTPD colonies. The Service believes that rodenticide use (including Rozol), while widespread in the BTPD range, in and of itself is not the determinate factor whether a black-footed ferret reintroduction can occur. Instead, it is the willingness of partners (private, State, Tribal and

Federal) to consider a reintroduction and then commit to manage a block of prairie dog habitat for black-footed ferret conservation. Most recent BTPD surveys indicate that there are many biologically suitable and potential reintroduction sites available, but the key to achieving black-footed ferret reintroductions and thus recovery is finding interested landowners and partners (FWS 2009b, Lockhart et al 2006, Luce 2006). Further, our experience is that landowners who are strong proponents of poisoning prairie dogs are not interested in participating in black-footed ferret reintroductions and, if Rozol was not available, they would likely use a different rodenticide. Therefore, the Service believes that Rozol use on BTPDs, with the agreed upon conservation measure to restrict Rozol use on future black-footed ferret reintroduction sites, will not eliminate future opportunities for reintroductions. Use of Rozol will not preclude black-footed ferret recovery.

c. Cumulative Effects

Cumulative effects include the effects of future State, Tribal, local, or private actions that are reasonably certain to occur in the action area considered in this BO. Future Federal actions that are unrelated to the proposed action are not considered in this section because they require separate consultation pursuant to Section 7 of the ESA.

Future rodenticide use, along with some land conversion from grasslands or rangeland into croplands or other development, is likely to continue in the range of the BTPD. With the black-footed ferret conservation measures in place, we do not believe that these actions will preclude conservation and recovery of the black-footed ferret because recent trends in BTPD occupied habitat are stable to increasing over large areas of the species' range (FWS 2009b). While Rozol use is likely increasing, its use may be supplanting some of the previously used prairie dog rodenticides. Thus, even though Rozol has been used for prairie dog control for nearly 2 decades in one state and for 5 to 10 years in others (Lee et al. 2005, EPA 2010b, 1993), it does not appear to be altering the stable to increasing prairie dogs trends found by the Service (FWS 2009b). Because the use of Rozol in black-footed ferret reintroduction sites will not be allowed, the impacts to current and future black-footed ferret reintroduction sites are not expected to be seriously impacted.

Within the black-footed ferret's range, which includes three species of prairie dogs, the Service believes that the availability of rodenticides will not prevent recovery of the black-footed ferret because recent analysis of the three prairie dog species indicates that those prairie dog species continue to inhabit millions of acres of habitat (FWS 2010c, 2009b, 2008c). As noted earlier, without adequate regulatory mechanisms, poisoning can affect current and future black-footed ferret reintroduction sites (FWS 2008b). While the total prairie dog acreage among the three species is much greater than is believed necessary to recover the black-footed ferret, much of the existing prairie dog acreage is not of a size or in a location to contribute to the black-footed ferret's recovery. The Black-footed Ferret Recovery Plan estimated that an average of 124 acres of prairie dog colonies is needed per black-footed ferret or approximately 185,000 acres of black-footed ferret occupied prairie dog habitat is needed to meet downlisting objectives for the species (FWS 1988). This acreage amount can be distributed between the three species of prairie dogs that encompass the black-footed ferrets' range (FWS 1988). While complete delisting

objectives for the black-footed ferret have not been finalized, it is likely that 500,000 acres of managed prairie dogs distributed between the three prairie dogs species would be sufficient to support delisting recovery objectives for the black-footed ferret (FWS 1988).

Another important factor affecting prairie dog populations and therefore black-footed ferret recovery is sylvatic plaque and the ongoing outbreaks which can result in widespread prairie dog die offs or, in some cases, more subtle deaths (Cully et al. 2010, Matchett et al. 2010). This exotic disease can directly kill black-footed ferrets that consume infected prairie dogs or eliminate black-footed ferret habitat among the three prairie dog species (Gage and Kosoy 2006, Godbey et al. 2006). At this time, the Service does not have information that Rozol use on BTPDs, in combination with other rodenticides and sylvatic plague, will prevent black-footed ferret recovery, but, in order to make informed decisions in the future, it will be important to have an understanding of the extent of Rozol use in each state.

d. Conclusion Regarding Jeopardy

After reviewing the current status of the black-footed ferret, the environmental baseline for the action area, the effects of the proposed action, and the cumulative effects, it is the Service's biological opinion that the use of Rozol as a BTPD rodenticide, which includes the black-footed ferret conservation measures, is not likely to jeopardize the continued existence of the black-footed ferret. No critical habitat for the black-footed ferret has been designated; therefore none will be affected. At this time, the Service believes that Rozol use on BTPDs, as modified through the agreed upon conservation measures will not preclude the conservation and recovery of the black-footed ferret even when combined with the use of other currently available legal rodenticides and our understanding of sylvatic plague.

In summary, this conclusion is based on the following:

- The modifications to the project description via the black-footed ferret conservation measures included in the EPA's letter of December 13, 2011 (EPA 2011c) and additional agreed upon conservation measures in April 2012, which ensure that:
    - Rozol use is prohibited in current and future black-footed ferret reintroduction sites; thus, we anticipate that survival of the species in the wild will not be compromised by this product.
    - Rozol use is prohibited in an area if an unknown wild black-footed ferret population is discovered.
    - Rozol restrictions on properties adjacent to reintroductions are minimized which lessens opposition to black-footed ferret reintroductions.
    - Rozol production quantities and distribution to locations within states will be provided to the Service which will allow an assessment whether the level of use could preclude recovery of the black-footed ferret.
- Sufficient prairie dog acreage exists among the three species of prairie dogs to support current Black-footed Ferret Recovery Plan downlisting objectives and likely future delisting objectives when those become finalized in the revised Recovery Plan.

GRAY WOLF

a. Status of the Species/Critical Habitat

Gray wolves from three separate populations are relevant to this consultation: 1) the Northern Rocky Mountains Distinct Population Segment (DPS) which encompasses the eastern one-third of Washington and Oregon, a small part of north-central Utah, and all of Montana, Idaho, and Wyoming; 2) the Western Great Lakes DPS which has a core area occurring in Michigan, Wisconsin, and Minnesota and a peripheral zone including eastern North Dakota, eastern South Dakota, northern Iowa, and a small portion of northern Illinois; and 3) the Mexican gray wolf which has been considered a subspecies and reintroduced into a NEP (under Section 10j of the ESA) area that includes portions of central Arizona, central and southern New Mexico, and a minute portion of western Texas, south of New Mexico.

In 1974-1976, the Service listed three subspecies of gray wolf (Northern Rocky Mountain gray wolf (*Canis lupus irremotus*), eastern timber wolf (*Canis lupus lycaon*) (FWS 1974), and Mexican wolf (*Canis lupus baileyi*)) (FWS 1976)) under the ESA, but in 1978 revised those regulations to list the entire gray wolf species as endangered, except in Minnesota where it was listed as threatened, in the coterminous United States (FWS 1978). At that time, the Service also designated critical habitat in Isle Royale, Michigan, and parts of northern Minnesota (FWS 1978). Since then, the Service has implemented numerous actions relative to the gray wolf, including development of recovery plans, identification of DPSs and NEPs, initiation of reintroductions and other recovery actions, and development of regulatory changes that have been subject to litigation in numerous Federal courts. For additional details and maps of these wolf recovery areas see: 1) Final Rule To Identify the Northern Rocky Mountain Population of Gray Wolf as a Distinct Population Segment and To Revise the List of Endangered and Threatened Wildlife (FWS 2009f), 2) Endangered and Threatened Wildlife and Plants; Revising the Listing of the Gray Wolf (*Canis lupus*) in the Western Great Lakes (FWS 2011f), 3) Final Rule; Establishment of a Nonessential Experimental Population of the Mexican Gray Wolf in Arizona and New Mexico (FWS 1998), and 4) Lower 48-State and Mexico Gray wolf (*Canis lupus*) listing, as revised, 5-Year Review: Summary and Evaluation (FWS 2012b).

Currently, gray wolves in the Northern Rocky Mountain DPS (including Montana and Idaho, as well as portions of eastern Oregon, eastern Washington, and north-central Utah, but excluding Wyoming) are removed from the List of Endangered and Threatened Wildlife and no longer receive protections under the ESA (FWS 2011g). Management of wolf populations in Montana and Idaho has been transferred to State authority. The Service has proposed to delist wolves in Wyoming (FWS 2011h). Wyoming has a management plan contingent upon necessary additional changes to Wyoming State law; Wyoming is anticipated to adopt the necessary statutory and regulatory changes within the next several months (FWS 2011h). Until then, wolves in Wyoming are protected by the ESA and considered a NEP designated under Section 10(j) which has increased the Service's flexibility and discretion in managing the gray wolf reintroduced population.

A final rule to remove wolves in the Western Great Lakes DPS from the list of Endangered and Threatened Wildlife was published in the Federal Register on December 28, 2011 (FWS 2011f), effective January 27, 2012. Management of wolf populations in Minnesota, Wisconsin and Michigan is now under the purview of those States.

Mexican gray wolves currently retain their original NEP, Section 10(j) status, and are protected by the ESA within the parameters established for that reintroduction effort (FWS 1998). Mexican gray wolves have been released annually into this population, and this practice will likely continue until natural reproduction sustains wild population growth.

While the open rangeland habitat of the BTPD does not coincide with the typical habitats (forested landscapes) used by gray wolf populations in the United States today, the ranges of the two species overlap when individual gray wolves disperse from their core populations. Those dispersing individuals are most relevant to this analysis. When wolves disperse from their packs and occur in other areas outside the boundaries of any DPS or Nonessential Experimental reintroduction area, their status under the ESA changes; they take on the listing status of the gray wolf in that area (wolves occurring in western North Dakota and South Dakota, Nebraska, Colorado, and other areas are considered endangered). Those wolves will remain protected by the ESA regardless of recent delisting actions in the Northern Rocky Mountain and Western Great Lakes DPSs, unless the Service makes additional regulatory changes in the future. Those wolves within Nonessential Experimental area boundaries (Wyoming and Arizona/New Mexico) retain ESA protections but with the management parameters established with the Section 10(j) rulemaking.

Critical habitat has been designated for the gray wolf but not within the action area. Due to a lack of overlap with the BTPD range, the Service agrees with the EPA that no critical habitat will be impacted by the proposed action; therefore, gray wolf designated critical habitat is not described herein.

(1) Species description

Gray wolves (*Canis lupus*) are the largest wild members of the dog family (Canidae). Adult gray wolves range from 18–80 kilograms (40–175 pounds) depending upon sex and region (Mech 1974). Smaller sizes tend to be found in the southern portion of wolf range (the Mexican wolf is the smallest extant wolf in North America) and larger sizes in the northern portion. Females weigh slightly less than males. Wolves reach adult size by 1 year of age. Wolves' fur color is frequently a grizzled gray, but it can vary from pure white to coal black. Mexican wolves are typically a patchy black, brown to cinnamon, and cream color, with primarily light underparts (Brown 1988). Solid black or white Mexican wolves do not exist as seen in other North American gray wolves.

(2) Life history

Elements considered relevant to this consultation are described below. Additional detailed information on the biology of this species is available in numerous documents within the literature cited of this document (e.g.,"Biology and Ecology of Gray Wolves" section of the April 1, 2003, final rule to reclassify and remove the gray wolf from the list of endangered and threatened wildlife in portions of the conterminous United States (FWS 2003).

(a) Range and habitat

Within North America, gray wolves formerly ranged from coast to coast with the exception of the mid-Atlantic states, the Southeast (areas occupied by the red wolf), and perhaps parts of California. They have historically been found in almost all habitat types, including the prairie and rangelands of the central United States where, coinciding with human settlement, most populations of wolves were extirpated by the early 1900s. In the coterminous 48 states today, they are found in the mostly forested lands of Minnesota, Wisconsin, Michigan, Montana, Idaho, and Wyoming, with the addition of the Mexican wolf reintroduction area in New Mexico, Arizona and a small part of western Texas. The Mexican wolf is endemic to the southwestern United States and Mexico. Once thought to need wilderness areas to survive, wolves can successfully occupy a wide range of habitats, though they tend to more readily occupy heavily forested areas and landscapes with low road densities (Mladenoff et al. 1995). The BTPD habitat is generally not considered preferred habitat by the gray wolf today; it offers little protective cover, and though individuals may traverse it quickly, they often do not survive human encounters in such areas. In Minnesota and Wisconsin, wolves are proving themselves more tolerant of human disturbance than previously thought and their range has expanded to include areas that are a mix of forest and agriculture. Essentially, wolves can live almost anywhere if they have abundant wild prey and if excessive numbers are not taken by humans.

(b) Prey items

Wolves are predators of primarily medium and large mammals. They may not eat for a week or more but are capable of eating 20 pounds of meat in a single meal. Wild prey species in North America include animals such as white-tailed deer (*Odocoileus virginianus*), mule deer (*O. hemionus*), moose (*Alces alces*), elk (*Cervus canadensis*), and other large ungulates. Wolves will also prey on mid-sized mammals, such as snowshoe hare (*Lepus americanus*) and beaver (*Castor canadensis*), with small mammals, birds, and large invertebrates sometimes being taken (Mech 1974, Stebler 1944, Wisconsin Department of Natural Resources 1999).

(c) Social nature and territory size

Wolves are social animals, normally living in packs of 2 to 12 wolves (but that number can vary considerably; pack sizes ranging into the 30s have been documented). The pack defends a territory that can be as large as 50 square miles or even extend up to 1,000 square miles in areas where prey is scarce. The pack consists of a breeding (top-ranking or alpha) pair, their pups from the current year, offspring from the previous year, and occasionally an unrelated wolf. Unrelated wolves are typically individuals dispersing from other packs.

(d) Dispersal

As indicated by the territory size described above, wolves often cover large areas and may travel as far as 30 miles a day. Although they trot at approximately 5 miles per hour (mph), wolves can attain speeds as high as 40 mph. By 3 years of age, many wolves disperse from the pack that they were born into to find mates and to expand into new areas. The animals have extraordinary dispersing ability, traveling over 600 miles, sometimes over large areas of inhospitable terrain. A wolf in Sweden with a Global Postitioning System (GPS) collar travelled a straight line distance of >1,092 kilometers (682 miles) with an actual travel distance of over >10,000 kilometers (6,000 miles) in just under a year (Wabakken et al. 2007). A wolf that dispersed from Gardiner, Montana, to western Colorado, where she was illegally killed by 1080 Compound poison in March 2009, travelled a straight line distance of 400 miles in 6 months, but daily GPS locations showed she actually walked over 3,000 miles (FWS et al. 2011).

Considerable information on wolf dispersal was obtained during 1993-2008, when 1,681 radio-collared wolves (858 males and 823 females) in the Northern Rocky Mountain DPS were tracked (Jimenez et al. 2011). The large sample size distinguishes that study; however, most of what was documented mirrored that already found by others (Fritts and Mech 1981, Boyd and Pletscher 1999, Mech 1987, Gese and Mech 1991, Boyd et al. 1995). Ten percent of the Northern Rocky Mountain wolf population dispersed annually; 297 known dispersals by 281 wolves were documented (some wolves dispersed and returned to their original pack up to three times). Many other dispersal events likely occurred during the Northern Rocky Mountain dispersal study but were undetected because only about 30 percent of the Northern Rocky Mountain wolf population was radio-collared by 2008 and it is difficult to detect lone dispersing wolves. Most wolves tended to move southward, but 55 dispersals occurred in an easterly direction. The dispersals could occur anytime during the year, but increases were noted in the fall with the peak occurring in January, and 58 percent (n=153) of all dispersals occurred between October and February (i.e., during the timeframe that Rozol may be applied) (Jimenez et al. 2011, unpublished data). Licht and Fritts (1994) studied 10 wolf mortality records in North Dakota and South Dakota between 1981 and 1992 and found that nine occurred in winter.

Dispersal distance by individual wolves in the Northern Rocky Mountain wolves study (Jimenez et al. 2011, unpublished data) was not as great as the species' potential, described above; mean dispersal distance for males was 98.1 kilometers (61 miles) and was not significantly different (P=0.11) than female dispersal distance at 87.7 kilometers (54.5 miles). However, in 10 instances, the wolves moved more than 186 miles which were considered to be unusually long distances (Jimenez et al. 2011, unpublished data). About 20 confirmed Northern Rocky Mountain wolf dispersal events from 1992-2010 have been over 190 miles with 4 wolves travelling beyond the Northern Rocky Mountain DPS border (FWS et al. 2011). The eastern edge of the Northern Rocky Mountain DPS is about 400 miles from the western edge (eastern Minnesota) of the Western Great Lakes DPS core area and is separated from it by hundreds of miles of unsuitable habitat in those Great Plains States (FWS 2009g). This propensity to disperse and the distances that have been recorded are the factors that lead the Service to believe that gray wolves could encounter and be exposed to Rozol-poisoned prairie dogs.

Dispersing wolves can have a lower survival rate than individuals that do not leave their packs (Jimenez et al. 2011, unpublished data), and those that disperse often die in proportionately higher numbers from human causes than those that do not disperse (Boyd and Pletscher 1999). Of 281 dispersing wolves in the Northern Rocky Mountain study, 166 (59 percent) survived dispersal to pair with another dispersing wolf to form new packs or to join new packs (Jimenez et al. 2011, unpublished data). The unusually long-distance dispersers typically do not find mates or survive long enough to form packs or to breed in the United States (FWS 2009f).

Human causes of mortality among dispersing wolves include illegal shootings, trapping, poisonings (e.g., M-44s intended for coyotes), and vehicle collisions. Dispersing wolves have been noted by the Service in Colorado in recent years with a likely vehicle collision mortality of an individual in 2004 and an illegal poisoning of another wolf in 2009 (via banned substance: Compound 1080). Of the 10 wolf mortalities documented in North Dakota and South Dakota from 1981-1992, 8 were mistakenly shot as coyotes, 1 was beaten to death after being chased by dogs, and another was shot by a hunter after the wolf allegedly attacked the man's horse as he was riding it (Licht and Fritts 1994). A wolf killed by a car near Sturgis, South Dakota, in 2006 was determined to have been from the Northern Rocky Mountain DPS. A wolf from the Western Great Lakes DPS was shot in Nebraska in 2003. A wolf (Minnesota origin) killed via a cyanide gun (M-44) intended for coyotes was documented in Harding County, South Dakota, in 2001. Other instances of mortality were noted in the Service's May 5, 2011, Proposed Rule To Revise the List of Endangered and Threatened Wildlife for the Gray Wolf (*Canis lupus*) in the Eastern United States, Initiation of Status Reviews for the Gray Wolf and for the Eastern Wolf (*Canis lycaon*) (FWS 2011j):

- *An adult male shot near Devil's Lake, North Dakota, in 2002.*
- *Another adult male shot in Richland County in extreme southeastern North Dakota in 2003.*
- *A wolf was shot in Roberts County, South Dakota, in January 2009.*
- *Another wolf was found dead in a foothold trap that was set as part of an ongoing USDA Wildlife Service's coyote control operation in southeastern Eddy County, North Dakota.*

Despite human-caused mortalities, populations have continued to increase in both numbers and range in both the Northern Rocky Mountain and Western Great Lakes DPSs. However, the Mexican wolf population has struggled to overcome this issue; 66 percent of all documented mortalities as of December 31, 2010, were human-caused, and these high mortality rates may reduce dispersing wolves below levels noted for other studied wolf populations (FWS 2011i).

(3) Population dynamics

Gray wolves are known to live up to 13 years in the wild and 15 years in captivity. Wolves typically breed as 2-year olds and may annually produce young until they are over 10 years old. Litter sizes range between 1-11 pups but generally include 4-6 pups (FWS 2003). Normally a pack has a single litter annually, but producing 2 or 3 litters in 1 year has been documented in Yellowstone National Park (FWS et al. 2002). The breeding season for wolves is from late January through March.

Breeding members of wolf packs can be quickly replaced either from within or outside the pack. Pups can be reared by another pack member should their parents die (Packard 2003, Brainerd et al. 2008, Mech 2006). Consequently, wolf populations can rapidly recover from severe disruptions, such as very high levels of human-caused mortality or disease. After severe declines, wolf populations can more than double in just 2 years if mortality is reduced; increases of nearly 100 percent per year have been documented in low-density suitable habitat (Fuller et al. 2003, Service et al. 2008, 2009f). Additionally, their extraordinary dispersal ability helps explain why wolves can recolonize even distant vacant suitable habitat relatively quickly and why their populations are resistant to extirpation (Mech and Boitani 2003, Adams et al. 2008).

Starting with an estimated 55 individuals that naturally colonized northwestern Montana in 1993, the Northern Rocky Mountain population grew an average of 25 percent annually between 1993 and 2008, with the assistance of reintroduction efforts in Wyoming and Idaho. At the end of 2009, the population estimate had grown to at least 1,706 wolves in 242 wolf packs and 115 breeding pairs (Bangs 2010). In 2010, that number was slightly down to 1,651 (FWS et al. 2011).

The Western Great Lakes DPS today is estimated to contain over 4,000 wolves, with the majority occurring in Minnesota. The Minnesota wolf population increased from an estimated 1,000 individuals in 1976 to 2,921 as of 2007-2008, and the estimated wolf range in the State has expanded by approximately 225 percent (FWS 2011j). Wolves were considered extirpated from Wisconsin in 1960 but began to recolonize in the 1970s, and an increase in the late 1980s has continued into 2011; the current population estimate there is 782 wolves (FWS 2011k, 2011f). With the exception of Isle Royale, wolves were extirpated from Michigan prior to the gray wolf listing, but wolves began to return in the late 1980s (Beyer et al. 2009), and wolf packs have continued to spread throughout Michigan's Upper Peninsula. Wolves are now found in nearly every county of Michigan's Upper Peninsula (Huntzinger et al. 2005), and 87 individuals were estimated to occur in Michigan in 2010-2011 (FWS 2011f).

The Mexican wolf reintroduction began in 1998 with the release of 11 individuals in the Blue Range Wolf Recovery Area of New Mexico and Arizona. The population has increased with a minimum end-of-year count peak of 59 wolves in 2006, via natural reproduction, translocations, and initial releases. At the end of 2010, the wild population totaled a minimum of 50 individuals (FWS 2012c).

With a minimum of 1,651 wolves in the Northern Rocky Mountain DPS in 2010 (FWS et al. 2011), an estimated 4,390 in the Western Great Lakes DPS (assuming the number of wolves in Minnesota has not changed substantially since 2007-2008, the date of the most recent estimate available for this analysis) (FWS 2011f) and a 2010 estimate of the Mexican wolf population at 50 (FWS 2012c), the total minimum estimate of wolves in these areas combined is approximately 6,091. Wolf population levels in the range of the BTPD are limited to dispersing wolves.

(4) Status, trends, and distribution

The decline and near extirpation of wolves from the lower 48 states in the early part of the 20th century was caused by a number of factors, including extreme control programs designed to eliminate the species. Factors in the eastern timber wolfs' decline included intensive human settlement, direct conflict with domestic livestock, lack of understanding of the animal's ecology and habits, and fears and superstitions regarding wolves and extreme control programs designed to eradicate it (Young and Goldman 1944, Mech 1970). These were a common thread among wolf populations in other areas of the United States as well. Land development (loss of habitat), impacts to prey base, poisoning, trapping, and hunting were also factors identified in the decline (FWS 1987). Mech (1995) indicates that primarily inadequate prey density and a high level of human persecution limit wolf distribution. In short, human-caused mortality is identified as the most significant issue to the long-term conservation status of wolves. Managing this source of mortality (i.e., overutilization of wolves for commercial, recreational, scientific and educational purposes and human predation) remains the primary challenge to maintaining a recovered wolf population into the foreseeable future (FWS 2009f).

In both the Northern Rocky Mountain and Western Great Lakes DPSs today, wolf numbers are trending upward but at slower rates than has been documented in the recent past. Available habitat appears to be reaching carrying capacity. The total population in the Northern Rocky Mountain DPS today is about five times higher than the minimum population recovery goal and three times higher than the minimum breeding pair recovery goal (FWS 2009f); the population has exceeded numeric and distributional recovery goals for about a decade. The Northern Rocky Mountain wolf population occupies nearly 100 percent of the recovery areas recommended in the 1987 recovery plan (FWS 1987) and nearly 100 percent of the primary analysis areas (the areas where suitable habitat was predicted to exist and the wolf population would live) analyzed for wolf reintroduction in central Idaho and the greater Yellowstone area (FWS 1994a). As mentioned above, wolves in the Northern Rocky Mountain DPS have been delisted in Montana, Idaho, Eastern Oregon, and Eastern Washington and are proposed to be delisted in Wyoming.

Relatively slow growth to stable populations in Minnesota, Wisconsin, and Michigan in recent years is indicative that available habitat is being filled in the Western Great Lakes DPS. Wolves in the Western Great Lakes DPS greatly exceed the recovery criteria (FWS 1992) for 1) a secure wolf population in Minnesota, and 2) a second population outside Minnesota and Isle Royale consisting of 100 wolves for 5 successive years. Based on the criteria set by the Eastern Wolf Recovery Team in 1992 and reaffirmed in 1997 and 1998 (FWS 2011j), the proposed DPS contains sufficient wolf numbers and distribution to ensure their long-term survival within the DPS, and this population has been delisted (FWS 2011f).

As mentioned above, the Mexican gray wolf population in New Mexico and Arizona has struggled to remain viable, and numbers remain very low. The NEP is currently not self-sustaining. A captive breeding program has been the source of Mexican wolves for reintroduction efforts to date. Currently, dispersing Mexican wolves are stringently managed. Individuals known to be from the reintroduced population are not allowed to establish territories outside the recovery area boundaries; they are captured and may be returned to the recovery area, put into the captive population, or otherwise managed according to existing provisions (FWS

1998). Mexico has recently initiated reintroductions of the Mexican wolf; in 2011, officials released five captive-bred Mexican wolves into the San Luis Mountains in Sonora just south of the United States-Mexico border (Bryan 2011). As of February 2012, four of the five released animals were confirmed dead due to poison (Albuquerque Journal 2012). Despite the initial setback, Mexico continues plan additional releases. If wolves from Mexico disperse into the United States, they will be considered endangered under the ESA, unless they establish themselves within the boundaries of the United States Mexican wolf experimental area, where they would be subject to the existing management provisions (FWS 1998).

The number of dispersing wolves from recovered wolf populations may currently be at its peak due to high wolf recovery numbers. As states take over wolf management, they will likely seek to achieve lower, but still viable, wolf population levels; thus, the number of dispersing wolves may decrease under state management plans. However, the Service believes there will still be some dispersing wolves from existing populations into areas where Rozol may be applied for prairie dog control. Areas within the BTPD range where the wolf remains protected are the locations where exposure to Rozol may occur that results in take of gray wolves.

(5) Analysis of the species likely to be affected

Any gray wolves protected by the ESA that disperse from known populations in existing (typically forested) occupied habitats into open rangelands where the BTPD exists (within the 10 States where Rozol may be applied) are the individuals of concern with the potential to be adversely affected by the proposed action. This may include reintroduced Mexican gray wolves that enter the United States from Mexico. Wolves in NEPs receive protections of the ESA per their specific rulemaking parameters. Wolves occurring outside of existing DPSs or NEPs take on the ESA status of the area that they are in.

As mentioned previously under the "Conservation Measures" section, in order to provide some protections for the Mexican gray wolf, the EPA and Liphatech agreed to preclude Rozol use from Catron, Grant, Hidalgo, and Sierra Counties of New Mexico which are part of the Blue Range Wolf Recovery Area. Prairie dogs occur in these counties but are primarily Gunnison's prairie dog (*Cynomys gunnisoni*); the BTPD is not common in these areas (Johnson et al. 2003), and prohibiting Rozol use on BTPDs will further reduce possible impacts to those reintroduction efforts. Dispersing wolves from the Mexican gray wolf reintroduced population are few, and individuals are typically translocated or killed. Thus, while Rozol use may still occur within the greater NEP area boundary, key areas of the reintroduction area will not have Rozol use. This conservation measure is anticipated to reduce the risk of adverse effects from Rozol use to the Mexican gray wolf.

Some level of wolf dispersal is expected from other recovered wolf populations, and the potential for endangered wolves to encounter Rozol in the proposed 10-state area of application exits. Documented gray wolf mortalities in the action area since 1981 (20 records were located for this analysis over a span of 31 years in the states of North Dakota and South Dakota (17), Colorado (2) and Nebraska (1)) have averaged approximately 0.65 wolves per year. These are documented wolf mortalities, but it is unknown how many gray wolves may disperse into the action area and not be reported.

(a) Environmental Baseline

(1) Status of the species within the action area

Gray wolves are not uniformly protected under the ESA throughout the range of the BTPD. Some wolf populations have been delisted, and wolves in Wyoming are proposed to be delisted. The exact number of dispersing wolves that may occur in the range of the BTPD where Rozol is proposed for use cannot be determined with certainty. The Service does not know of wolf populations in the range of the BTPD except for the reintroduction efforts in southwestern New Mexico. The Service recognizes that dispersing wolves can occur throughout the BTPD range and could be exposed to Rozol use.

(2) Factors Affecting Species Environment within the Action Area

Throughout the range of the wolf, generally three factors dominate wolf population dynamics: food, people, and source populations (Fuller et al. 2003). Among those three factors and within the BTPD range, people likely have the greatest influence on dispersing wolves. Traveling wolves must cross numerous stretches of roads and may be struck by vehicles. In addition to such vehicle-caused mortality, road access to wolf habitat generally increases the risk of other human-related mortality of wolves, including shooting and trapping (Mech et al. 1988; Fuller 1989). When individual wolves appear in areas not known to harbor packs, they are often mistaken for coyotes and shot. Wolves become particularly vulnerable to this type of mortality when they occur in open rangelands, far from the protective cover of forested areas they usually inhabit. Cases of livestock depredation by dispersing wolves have also been documented, and those wolves are often killed as well. Ongoing animal damage control activities by the United States Department of Agriculture and/or state agencies in the action area that target coyotes may instead kill wolves in accordance with established wolf depredation plans. While these factors affecting dispersing wolves are not expected to influence the existing healthy wolf populations from which they came, in the dispersal areas, wolves may not survive long due to human-caused mortality. Dispersing wolves are likely to encounter many forms of threats when they leave their core areas, and high wolf mortality rates in the BTPD range are likely irrespective if Rozol is being used. We currently have no documented Rozol-related mortalities of gray wolves.

(b) Effects of the Action

(1) Factors to be considered

According to the BA (page 107), chlorophacinone exposure to the gray wolf is expected as the wolf range overlaps BTPD and gray wolf prey items may include animals poisoned by Rozol, including small mammals, birds and large invertebrates. The EPA determined that adverse direct effects to the gray wolf are likely based on calculated RQs that included 24.82 for exposure to non-target animals and 9.59 for exposure to BTPDs (Table 1.1, page 21, of the BA). In their *Risk Quotient Methods and Levels of Concern* submitted for this consultation, the EPA further estimates that the gray wolf would only need to consume less than 1 poisoned mouse or less than 1 poisoned BTPD every day for 5 days to exceed a 0.1 LOC for endangered species. On page 21 of the BA (Table 1.1), the EPA states that "growth and reproductive effects cannot be precluded due to the absence of chronic data; however, growth and reproductive effects are not expected

because mortality typically occurs as a result of acute exposure." Table 1.1 of the BA also describes potential indirect effects due to the loss of prey base. The Service agrees that Rozol use on BTPDs could adversely affect dispersing wolves.

(2) Analyses for the effects of the action

The effects to dispersing gray wolves in the action area are most likely to be indirect, i.e., secondary poisoning via consumption of Rozol-poisoned live animals or carcasses. It is suspected that wolves would consume dead or dying prairie dogs if they are encountered above ground and may also excavate and consume prairie dogs that are buried or die underground. The frequency at which a dispersing wolf might encounter a Rozol-poisoned area is unknown and would depend on a variety of factors such as the prevalence of Rozol use in the area, the type of habitat traveled by the wolf, the distance traversed, and the availability of other prey items.

Although there are no previous reports of gray wolf exposure to chlorophacinone rodenticides, other canines (including kit foxes and coyotes), in addition to an American badger, have been found dead in association with Rozol applications (Ruder et al. 2011). Although these animals are smaller than a wolf, they are all opportunistic predators and scavengers like wolves. If multiple dead and dying prairie dogs and other non-target small mammals were available for consumption, a wolf would likely take advantage of that situation. Effects of chlorophacinone exposure to the gray wolf when individuals do encounter a Rozol-poisoned prairie dog colony would likely be similar to those seen in domestic dogs suffering from anticoagulant rodenticide toxicosis which include shortness of breath, hemoptysis (i.e., the spitting up of blood from the lungs), pallor (i.e., reduced amount of oxyhaemoglobin in skin), and lethargy (Sheafor and Couto 1999, Murray and Tseng 2008). The EPA's use of an adjusted LD 50 of 0.03 mg/kg to evaluate risk to gray wolves is much more conservative than using the chlorophacinone LD_{50} range of 50-100 mg/kg for dogs (EPA 2010b).

The Service agrees with the EPA that a wolf that encounters a Rozol-poisoned BTPD colony could receive a LD_{50} from consuming poisoned prairie dogs. The extent of effects and severity of response by a gray wolf to consumption of Rozol-poisoned animals would depend in part on the amount of Rozol ingested over time because most animals experience greater adverse effects from multiple doses of chlorophacinone. Repeat exposure could occur if a dispersing wolf remains near a Rozol-poisoned prairie dog colony and obtains multiple meals from it. Receiving a LD_{50} may take more than one poisoned prairie dog. Sub-lethal effects may occur if a wolf leaves a prairie dog town before consuming a LD_{50} or if timing is such that it does not find enough Rozol-poisoned animals to consume. However, little information is available regarding sub-lethal effects, and Rozol is known to be an effective anticoagulant. It seems likely that death would be the likely result for a gray wolf that ingests Rozol, either directly through hemorrhaging or sub-lethal impairment of behavior (e.g., breeding, feeding and sheltering), that eventually leads to its demise.

It is the Service's opinion that indirect effects to the gray wolf due to the loss of prey base from use of Rozol are not cause for concern regarding effects to wolves because prairie dogs are not known to be a significant dietary item for the gray wolf which normally does not inhabit BTPD areas. Dispersing individuals are anticipated to come upon BTPD colonies only opportunistically as they travel.

(3) Species' Response to the Action

Because the number of wolves dispersing into the action area is anticipated to be very low (as indicated above, we are aware of 20 gray wolf mortalities over 31 years in the action area), population-level effects are not anticipated. Most of the habitat within the action area is not important for wolf recovery, and we do not expect populations to become established in these areas. Lethal control of wolves in North Dakota and South Dakota has been determined to have no adverse effects on the long-term viability of wolf populations in the delisted Western Great Lakes DPS because the existence of a wolf or a wolf population in the Dakotas would not make a meaningful contribution to the maintenance of the current viable, self-sustaining, and representative metapopulation of wolves in the Western Great Lakes DPS (FWS 2011j). The same may be said for wolves dispersing from the Northern Rocky Mountain DPS. The potential impact to the Mexican gray wolf population within the area occupied by wolves is not expected to be great, given the EPA's adopted conservation measure to prohibit Rozol use in counties within the core reintroduction area, the ongoing intensive management (capture and return of dispersing wolves to reintroduction area) that inhibits dispersal of Mexican gray wolves, relative lack of preference by wolves for the open country typical of BTPD colonies, and risk posed to wolves that occur in such habitats where they are highly visible and vulnerable to more direct forms of human mortality (i.e., shooting). However, within the 15-year timeframe for which this BO is applicable, it is possible for reintroduced Mexican gray wolves to enter the United States via Mexico's reintroduction efforts, and Mexican gray wolves in New Mexico may expand their populations beyond the current 10(j) boundaries. If Rozol use is determined to result in wolf mortality beyond the low levels anticipated herein, such mortality could impede recovery of the Mexican gray wolf (FWS 1982). With the exception of the Mexican gray wolf population, individual gray wolves lost to Rozol poisoning are not anticipated to incur population level effects to the species. In the absence of human-induced mortalities and presence of adequate prey, gray wolves are a resilient species demonstrating relatively fast recovery rates after population declines. However, due to the diminished status of the Mexican gray wolf population, take of any wolves in New Mexico due to Rozol is of increased concern and could affect the ability of wolves to expand their populations.

(a) Cumulative Effects

Cumulative effects include the effects of future state, tribal, local or private actions that are reasonably certain to occur in the action area considered in this BO. Future Federal actions that are unrelated to the proposed action are not considered in this section because they require separate consultation pursuant to Section 7 of the ESA.

The level of human activities in the action area today is anticipated to continue and perhaps increase as human populations continue to expand. Farming and ranching is prevalent in the range of the BTPD and will continue into the foreseeable future. The Service anticipates high mortality rates for gray wolves that disperse in the BTPD range. Such wolves occurring outside of their current cores ranges are likely to be intentionally or unintentionally killed via such mechanisms as vehicle collisions, poisoning, and shooting which will likely prevent recolonization of significant areas of the BTPD range. Cumulatively, wolf populations have continued to rise in the face of these factors, except for the Mexican gray wolf population. For

Mexican gray wolves, any additional mortality, when combined with the effects of the proposed action, is a cause for concern. However, we do not believe that it is to the level that would preclude recovery of the Mexican gray wolf, due to the low value of the open habitats preferred by BTPDs for the wolf.

(b) Conclusion Regarding Jeopardy

After reviewing the current status of the gray wolf, the environmental baseline for the action area, the effects of the proposed use of Rozol to control BTPDs in 10 western states, and the cumulative effects, it is the Service's biological opinion that the action, as proposed, is not likely to jeopardize the continued existence of the gray wolf. Critical habitat has been designated but does not occur in or near the action area; therefore, none will be affected. Our conclusion was based primarily on the following factors:

- Gray wolves dispersing into the action area are a very small portion of existing gray wolf populations, and such individuals are typically precluded from establishing packs and territories due partly to high mortality rates.
- Dispersing wolves in the BTPD range are not considered critical to the recovery of wolf populations in the United States and, cumulatively, gray wolf populations have continued to increase despite losses of dispersing individuals.
- The BTPD colonies are not typical habitat for the gray wolf, dispersing individuals are not anticipated to remain in such areas for long, and lack of cover for gray wolves within BTPD habitat often results in increased vulnerability to other mortality factors such as shooting.
- Gray wolf populations are considered recovered by the Service in the Northern Rocky Mountain and Western Great Lakes DPSs; delisting has occurred, and future delisting in Wyoming is proposed.
- The conservation measure by the EPA to preclude Catron, Grant, Hidalgo, and Sierra Counties in New Mexico from Rozol use is protective of the Mexican gray wolf. Impediments to recovery may be possible in the future if Mexican wolf populations expand into new areas and Rozol-related mortalities are determined to exceed currently anticipated levels for the Mexican gray wolf, but a low number of Mexican gray wolves are expected to be affected by the action at this time.

NORTHERN APLOMADO FALCON

a. Status of the Species/Critical Habitat

The northern aplomado falcon (*Falco femoralis septentrionalis*) is one of three subspecies of the aplomado falcon and is the only one of those recorded in the United States. This subspecies was listed by the Service as an endangered species on February 25, 1986 (FWS 1986). It once extended from Trans-Pecos Texas, southern New Mexico and southeastern Arizona, to Chiapas and the northern Yucatan along the Gulf of Mexico and along the Pacific slope of Central America north of Nicaragua (FWS 1990). Northern aplomado falcons were fairly common in suitable habitat throughout these areas until the 1940s. However, they subsequently declined

rapidly and became extirpated from the United States after 1952. The last documented nesting pair of wild northern aplomado falcons in the United States was in Luna County, New Mexico, in 1952.

The decline of the northern aplomado falcon was caused by widespread shrub encroachment resulting from control of range fires and intense overgrazing (FWS 1986, Burnham et al. 2002), and large-scale agricultural development in grassland habitats used by the northern aplomado falcon (Heady 1994, Keddy-Hector 2000). Pesticide exposure was likely a significant cause of the subspecies' extirpation from the United States with the initiation of widespread use of organochlorine pesticides, such as DDT (dichlorodiphenyltrichloroethane) and DDE (dichlorodiphenyldichloroethylene), after World War II which coincided with the northern aplomado falcon's disappearance (FWS 1986). Northern aplomado falcons in Mexico in the 1950s were heavily contaminated with DDT residue, and these levels caused a 25 percent decrease in eggshell thickness (Kiff et al. 1980). Such high residue levels can often result in reproductive failure from egg breakage (FWS 1990). Use of organophosphate insecticides may also threaten northern aplomado falcons because insects and small, insectivorous birds are the species' preferred prey items (Keddy-Hector 2000). Collection of northern aplomado falcons and their eggs may have also been detrimental to the subspecies in some localities. However, populations of birds of prey are generally resilient to localized collection pressure (FWS 1990).

Little is known about the migratory behavior or seasonal movements of northern aplomado falcons (Service 1990). Nesting chronology is somewhat variable with egg-laying recorded from January to September, although eggs are usually laid during the months of March to May. Northern aplomado falcons do not build their own nests, but use nest sites constructed by corvids such as Chihuahuan ravens (*Corvus cryptoleucus*) or by large raptors. Thus, northern aplomado falcons are dependent on nesting activities of other stick nest-building birds and their habitat requirements. Nest sites are found in structures such as multi-stemmed yuccas (*Yucca torreyi* and *Yucca elata*) and large mesquite trees (*Prosopis* spp.) as well as other trees.

Northern aplomado falcons feed on a variety of prey, including birds, insects, rodents, small snakes, and lizards. Ligon (1961) suggested that the food habits of northern aplomado falcons "consisted almost wholly of small reptiles, lizards, mice, other rodents, grasshoppers, and various other kinds of insects, rarely small birds except in winter when other food is lacking." Therefore, in winter, factors affecting habitat suitability for migratory bird species may also affect the suitability of the habitat for northern aplomado falcons which in turn can affect the potential for survival of northern aplomado falcons (FWS 2002b). In eastern Mexico, small birds accounted for 97 percent of total prey biomass, but insects represented 65 percent of prey individuals (Hector 1985). In one study, 82 bird species were found in prey remains; of these, the most common were meadowlarks (*Sturnella* spp.), common nighthawks (*Chordeiles minor*), northern mockingbirds (*Mimus polyglottos*), western kingbirds (*Tyrannus verticalis*), brown-headed cowbirds (*Molothrus ater*), Scott's oriole (*Icterus parisorum*), mourning doves (*Zenaida macroura*), cactus wrens (*Campylorhynchus brunneicapillus*), and pyrrhuloxia (*Cardinalis sinuatus*), suggesting a preference for medium-sized songbirds (FWS 2002b). Documented invertebrate prey includes grasshoppers, beetles, dragonflies, cicadas, crickets, butterflies, moths, wasps, and bees (FWS 1990). Differences in prey abundance and nest site availability can cause differences in home range size. Based on several studies, the Service estimates the northern

aplomado falcon home range size to be approximately 34 square km^2 (8,401 acres) (FWS 1990, 2002b). For management purposes, this area can be described by a circle with a radius of 3.2 km (2 mi) around a particular habitat feature (e.g., a nest site).

Northern aplomado falcon habitat is variable throughout its range and includes palm and oak savannahs, various desert grassland associations, and open pine woodlands. Within these variations, the essential habitat elements appear to be open terrain with scattered trees, relatively low ground cover, an abundance of insects and small to medium-sized birds, and a supply of nest sites (FWS 1990). In Mexico, reported habitat includes palm and oak savannas, open tropical deciduous woodlands, wooded fringes of extensive marshes, various desert grassland associations, and upland pine parklands (FWS 1990). The historical range of the northern aplomado falcon in Texas, New Mexico and Arizona occurs within the Chihuahuan Desert which is comprised of three basic community types: desert scrub, desert grasslands, and woodlands. The species' historical range also occurs in the coastal prairies of southern Texas.

Northern aplomado falcons are primarily associated with open grasslands that include scattered mesquite and/or yuccas, although small patches of scrub and woodlands may be used (FWS 2006f). Existing data suggest that the ecological status of Chihuahuan Desert grasslands currently occupied by northern aplomado falcons is high seral to potential natural community or climax with significant basal cover of grass species. Montoya et al. (1997) reported the occupied nesting habitat as having basal ground cover ranging from 29 to 70 percent with a mean of 46 percent. Woody plant density ranged from 5 to 56 plants per acre with a mean of 31 plants per acre. Dominant woody plant species, comprising 74 percent of this community, were Mormon tea (*Ephedra viridis*), soaptree yucca (*Yucca elata*), sacahuista (*Nolina microcarpa*), mesquite, senecio (*Senecio* spp.), creosotebush (*Larrea tridentata*), and baccharis (*Baccharis* spp.). Site-specific habitat assessments should be conducted to further define whether the site of a given project or activity occurs within suitable habitat for this species.

In recent times, the intense overgrazing that resulted in shrub encroachment into grasslands has moderated, and improved range management techniques have been developed, including decreased stocking rates, stock rotation, prescribed burning, and other brush control methods (Archer 1994, Heady 1994, Burnham et al. 2002). Furthermore, the use of DDT was banned in the United States in 1972 and in Mexico in 2000. Present threats to the northern aplomado falcon including long-term drought and continued replacement of grassland communities with shrubs in Chihuahuan Desert grasslands. Additionally, large-scale conversion of grasslands to agriculture and the increased presence of the great-horned owl (*Bubo virginianus*), which preys upon the northern aplomado falcon, may be limiting recovery of this subspecies (Macías-Duarte et al. 2004, FWS 2006g). In contrast to these current threats, northern aplomado falcons appear to be relatively tolerant of human presence. They have been observed to tolerate approach to within 100 m (328 ft) of their nests by researchers, have nested within 100 m (328 ft) of highways in eastern Mexico (Keddy-Hector 2000), and are frequently found nesting in association with well-managed livestock grazing operations in Mexico and Texas (Burnham et al. 2002). Burnham et al. (2002) concluded that northern aplomado falcons would be able to coexist with most current land-use practices in the United States on the broad scale.
A recovery plan for the northern aplomado falcon was finalized by the Service in 1990 (FWS 1990). The objective of the Aplomado Falcon Recovery Plan is to ensure that the northern

aplomado falcon is no longer threatened by habitat loss, pesticide contamination, or human persecution. Implementation of the steps outlined in the Aplomado Falcon Recovery Plan could lead to downlisting the northern aplomado falcon from endangered to threatened by 2030.

To address reestablishment of northern aplomado falcons in the United States, reintroduction of nestling northern aplomado falcons was identified by the Aplomado Falcon Recovery Plan as a recommended methodology. To further aid reestablishment, reintroduction sites are carefully selected to optimize habitat suitability. Northern aplomado falcon reintroductions have been ongoing in southern Texas since 1985 on National Wildlife Refuges and private land under Safe Harbor Agreements. Consequently, by 2005, reintroductions had resulted in at least 44 pairs of northern aplomado falcons in southern Texas and adjacent Tamaulipas, Mexico, where no pairs had been recorded since 1942 (Jenny et al. 2004). The first nesting pair of northern aplomado falcons in south Texas subsequent to releases did not occur until 1995; however, by 2005, the Texas pairs had successfully fledged more than 244 young (Juergens and Heinrich 2005). In 2008, The Peregrine Fund found that 31 out of 38 territories surveyed in southern Texas were occupied (The Peregrine Fund 2009). There are likely more breeding pairs present in this area than what has been documented, considering areas of habitat that are inaccessible for surveys. Reintroduction of captive-bred northern aplomado falcons began in west Texas in 2002. The Peregrine Fund reported up to 10 breeding pairs were found in west Texas in 2009, including pairs that successfully reproduced (Heinrich 2010).

Reintroduction of captive-bred northern aplomado falcons began in New Mexico with the release of 11 birds in 2006 on the privately-owned Armendaris Ranch near Truth or Consequences. In 2007, a pair of northern aplomado falcons from this first year of reintroductions produced two fledglings on the ranch. In 2007, a total of 41 birds were released in New Mexico on private, State, Bureau of Land Management, and Department of Defense lands. Releases are planned to continue through 2015 with up to 150 northern aplomado falcons released in New Mexico each year.

To date, 686 young falcons have been released in west Texas and 305 falcons in southern New Mexico in unfragmented native grasslands on private, State, and federally-managed areas. Northern aplomado falcons in New Mexico and Arizona are included in a NEP designation under Section 10(j) of the ESA (Service 2006f). When NEPs are located outside a National Wildlife Refuge or unit of National Parks, they are treated as proposed for listing and only two provisions of Section 7 apply: Section 7(a)(1) and Section 7(a)(4). Section 7(a)(4) requires Federal agencies to confer, rather than consult, with the Service on actions that are likely to jeopardize the continued existence of a proposed species. The results of a conference are advisory in nature and do not restrict agencies from carrying out, funding, or authorizing activities. Northern aplomado falcons have been reintroduced in Texas on private lands using Safe Harbor Agreements, and their regulatory status under the ESA is endangered. Therefore, Section 7(a)(2) consultation by Federal agencies applies to aplomado falcons in Texas.

Currently, there are approximately 36 aplomado falcon pairs in the United States, which constitute less than two-thirds of the minimum number of 60 self-sustaining breeding pairs in suitable parts of the southwestern United States recommended by the 1990 Recovery Plan for reclassification of the subspecies to threatened status. The great majority of these breeding pairs currently occur outside the action area of this project in south Texas due to higher prey availability in the coastal region. Over the course of this 15-year project, the Service expects more breeding pairs to establish in New Mexico and west Texas.

b. Environmental Baseline

Formal surveys and reliable sightings submitted to the Service show that a small number of northern aplomado falcons have been sighted in the United States during every decade since the 1960s (FWS 2006f). In addition, a resident pair of northern aplomado falcons in Luna County, New Mexico, bred successfully in 2002, fledging three young. These were the first known northern aplomado falcons produced in either New Mexico or Arizona since the subspecies' extirpation as a breeding species in the 1950s. Another pair was reported near this site in 2002, but no nest was located and only one of the pair was present 2 days later (Meyer and Williams 2005). The 2002 nest represented the first successful reproduction by naturally occurring northern aplomado falcons in the United States in 50 years. Meyers and Williams (2005) reported at least eight individual northern aplomado falcons in Luna County between 2000 and 2004. The species occurred historically in Hidalgo County, and there have been five reports of northern aplomado falcons in or near the Animas Valley from the 1990s through the early 2000s (Meyer and Williams 2005).

(1) Status of the species within the action area

The action area for this consultation includes the historic range of the BTPD in the United States and counties adjacent to that range. The northern aplomado falcon is currently found in Texas and New Mexico as well as Guatemala and Mexico. Therefore, the portion of the action area of concern for the northern aplomado falcon includes only New Mexico and Texas where the range of this species coincides with the proposed use of Rozol to control BTPDs in the United States.

Northern aplomado falcons in New Mexico were designated a 10(j) NEP to encourage landowners to support the reintroduction of northern aplomado falcons in the state. Several landowners have supported reintroduction and manage the introduction areas to promote northern aplomado falcons. Under the 10(j) rule, northern aplomado falcons do not have incidental take restrictions on private lands. In Texas, private landowners that have allowed releases of northern aplomado falcons on their property are party to a Safe Harbor Agreement (FWS 1996 and 2000a) that covers the entire area within 30 miles of each release site. Under the Safe Harbor Agreement program, participating landowners are permitted to take northern aplomado falcons incidental to future lawful land-use actions (such as prairie dog control), provided that the landowner maintains any established baseline responsibilities (FWS 2000b). All northern aplomado falcon release sites and all recorded nests and northern aplomado falcon pairs within the action area in Texas occur on lands covered by the Safe Harbor Agreement (Montoya 2011, personal communication).

(2) Factors affecting species environment within the action area

The loss of or physical degradation of conditions in occupied habitat or in potential reintroduction sites would compromise the reintroduction program and recovery of the northern aplomado falcon. While the NEP in New Mexico and Arizona is not necessary for the continued survival of the species, it provides the benefit of an additional population in the event of a catastrophic loss of populations in Texas.

Sources of loss and degradation of nesting and roosting sites may include land use and human activities. The activities described below are common sources of stressors that affect the conservation of the northern aplomado falcon.

(a) Land use

Land use activities affect the distribution, density, and species composition of the native vegetation communities on the landscape. Land clearing (including for facilities, roads, trails and utility corridors) eliminates the vegetation, livestock grazing reduces the biomass of desired species and promotes others (that may have differing densities on the ground as well), ground or surface water depletion eliminates riparian and marsh vegetation communities, and erosion can eliminate plants along the paths of gullies.

(b) Livestock grazing

There has been considerable literature produced on the effects of livestock grazing on natural vegetation communities in the desert Southwest. Desert shrublands, grasslands, and woodlands in arid areas face certain threats from any land use that affects the surface and vegetation community.

Currently, the intense overgrazing that resulted in shrub encroachment in the Chihuahuan Desert grasslands in New Mexico and Arizona has moderated, and improved range management techniques have been developed and implemented, including decreased stocking rates and stock rotation. Techniques to increase the incidence of beneficial fire, to restore and increase vegetative productivity, to control erosion, and to suppress brush encroachment have been widely implemented in this planning unit. Among these are managed fire (including prescribed burns), various types of erosion control structures, and various types of brush control measures (Archer 1994, Heady 1994, Burnham et al. 2002). In addition, livestock management on Federal lands must now also consider other public resources. Within this planning unit, many private landowners and public land managers maintain well-managed livestock grazing programs that are compatible with northern aplomado falcon nesting and roosting and maintenance of reintroduction habitat suitability.

(c) Road construction, maintenance, and use

Construction and maintenance of access roads has a significant effect on the landscape. Roads and trails provide for foot or vehicle access to the landscape for a variety of purposes that often have other effects on soils, water features, vegetation communities, and wildlife.

(d) Communications towers and power lines

Although the effect of communication towers and power lines on the northern aplomado falcon is not well documented, these structures can have an adverse effect on bird species in general, and raptors in particular, due to collision or electrocution. Although birds can collide with any part of a communication tower, causing injury or death, they are most likely to collide with unmarked guy wires, which can be difficult to see. Northern aplomado falcons may also collide with power lines, especially if the power lines are unmarked. Power lines that are uninsulated may electrocute northern aplomado falcons if they try to use them to perch on or collide with them. Northern aplomado falcons may be particularly vulnerable to collision with such objects as they tend to "engage in high-speed, low-level, reckless pursuits of swift avian prey" (Keddy-Hector 2000).

(e) Organochlorine and organophosphate pesticide contamination

In the past, organochlorine compounds (DDE/DDT) were heavily used in pesticide applications in the agricultural areas surrounding northern aplomado falcon habitat in south Texas. It is unclear to what degree residual chemicals may still be present in the species' prey base, although some evidence indicates that this may be a lingering threat (Mora et al. 1997, Keddy-Hector 2000). In addition, organophosphate insecticides may threaten the species through adverse effects on its primary prey base of insects and small insectivorous birds, particularly in agricultural areas of south Texas.

c. Effects of the Action

The RQ calculated by the EPA for the northern aplomado falcon, based on the LC_{50} value of 56 mg active ingredient per kilogram diet, was 0.104 for consumption of non-target animals. A LOC of 0.1 for the RQ is set for listed species (EPA 2010b). Because the RQ of 0.104 exceeds the LOC, the EPA determined that there is potential for risk of acute adverse effects to northern aplomado falcons from exposure to Rozol (EPA 2010b). The BA states that the northern aplomado falcon would have to consume 5 poisoned mice or less than 1 poisoned BTPD to reach the LOC and are more likely to consume mice than BTPDs. The BA also states that, because no avian reproduction studies have been conducted, risk cannot be precluded at any level.

While there is no avian reproductive study to help estimate risk, external bleeding, fatigue, internal hemorrhaging, and increased blood coagulation has been reported in studies of secondary exposure to birds (see section on "Indandione Mode of Action and Toxicity" above). Additionally, chlorophacinone is a first generation rodenticide, and consecutive intake over multiple days tends to reduce the amount that results in LD_{50}. Thus, BTPDs and non-target species such as mice can accumulate a "super dose" prior to expiring or becoming intoxicated and predated upon by birds such as the northern aplomado falcon. It could take less than 5 mice or 1 BTPD to intoxicate a northern aplomado falcon. However, due to its relatively small size, the northern aplomado falcon is not likely to take prey as large as a BTPD, and the northern aplomado falcon is not known to scavenge.

As described in the "General Background" section above, raptors such as the northern aplomado falcon may be especially sensitive to Rozol per our previous discussion in the "Rozol Exposure and Effects Assessment" section. Although toxicity data for chlorophacinone effects to raptors

are lacking, toxicity tests with diphacinone indicate that some raptors are 20-30 times more sensitive than the two test species, northern bobwhite quail and mallard duck, required by the EPA for pesticide registration (Rattner et al. 2010a, 2011a, 2011b). Given the similarity of chlorophacinone to diphacinone, we believe that the northern aplomado falcon is more sensitive to Rozol than was estimated in the BA using bobwhite quail LC_{50} data. Therefore, acute and sub-acute risks to the northern aplomado falcon are likely higher than assessed in the BA.

If individual northern aplomado falcons were to enter a BTPD colony, exposure to chlorophacinone via consumption of primary consumers of Rozol bait may occur. The falcons are not known to consume carrion, but Rozol poisoning of this species is possible via consumption of live mammals and birds that have fed on Rozol bait. As mentioned previously, the evidence of Rozol exposure to horned larks and a meadowlark from a field application of Rozol (Vyas 2010a) indicate that predation of songbirds that have consumed Rozol bait is a likely route of exposure to northern aplomado falcons. In addition to small birds, which the falcon may prey on preferentially in the winter when other food is lacking, the food habits of the northern aplomado falcon consist of small reptiles, lizards, mice, other rodents, grasshoppers and other insect species. In eastern Mexico, small birds accounted for 97 percent of total prey biomass, but insects represented 65 percent of prey individuals (Hector 1985). In one study, 82 bird species were found in prey remains suggesting a preference for medium-sized songbirds, although birds over 500 g have been recorded (FWS 2002b).

Following treatment with Rozol, northern aplomado falcons may experience repeated doses of Rozol-exposed prey. During a Rozol treatment, dead and dying primary consumers (i.e., BTPDs, other small mammals, and birds) were visible in colonies 9 days after treatment and were still present when the study ended at day 29 post-treatment (Vyas 2010a). Additionally, raptors may preferentially fed at prairie dog colonies treated with Rozol compared to untreated colonies (Vyas 2010a). This effect has been observed in predators previously. Kestrels preferentially catch prey displaying aberrant behavior following pesticide exposure compared to healthy prey (Hunt et al. 1992). The northern aplomado falcon may also be attracted to Rozol-treated prairie dog colonies if they provide a source of easy meals of either rodents or birds species.

Northern aplomado falcons experiencing secondary exposure to chlorophacinone are likely to experience mortality or sub-lethal effects which may result in behavioral changes affecting feeding, breeding, or sheltering activities of individuals. The effects of toxicity could be influenced by other stressors, such as previous exposure and retention of pesticides, including other anticoagulants.

Because raptors may be highly sensitive to Rozol, non-target exposure is also likely to reduce the availability of large raptor nests that northern aplomado falcons require for nesting. As described above, northern aplomado falcons do not build their own nests but use nests constructed by corvids or large raptors. These large predators can successfully predate or scavenge prairie dogs that have eaten Rozol-contaminated bait. When these predators are killed by exposure to Rozol, the number of stick nests available to northern aplomado falcons for nesting is also reduced. This may cause northern aplomado falcons to expend more time, energy, and risk to locate suitable nesting substrate, or they may find no suitable nests and forego breeding altogether.

Actual exposure is expected to be minimal due to the low density of BTPD colonies within the northern aplomado falcon's range. In addition, in areas where the northern aplomado falcon has been reintroduced in Texas, landowners have signed cooperative agreements with the Service and The Peregrine Fund to maintain northern aplomado falcon habitat at or above baseline levels and are responsible to notify these organizations before performing land use practices that may adversely affect the northern aplomado falcon. For these reasons, we expect the frequency of northern aplomado falcons encountering Rozol-treated BTPD colonies to be low, and few northern aplomado falcons would experience sub-lethal effects or mortality from consuming Rozol-exposed prey.

However, we also anticipate that detection of Rozol-poisoned northern aplomado falcons will be rare. The birds are highly mobile; debilitated, dying, or dead falcons, particularly when they move away from Rozol-poisoned prairie dog colonies, are likely to go unreported. Rozol has been used for BTPD control in Texas since 2006 under a SLN label. While we are unaware of any incidents involving Rozol and the northern aplomado falcon, we recognize the vastness of the area involved and the difficulty in locating Rozol-affected raptors such as northern aplomado falcon.

d. Cumulative Effects

Cumulative effects include the effects of future State, tribal, local or private actions that are reasonably certain to occur in the action area considered in this BO. Future Federal actions that are unrelated to the proposed action are not considered in this section because they require separate consultation pursuant to Section 7 of the ESA.

Human activities may affect the northern aplomado falcon and result in direct and indirect mortality, habitat loss, or reduction of habitat suitability. Anthropogenic uses of northern aplomado falcon habitat include ungulate grazing, recreation, fuels reduction treatments, resource extraction (e.g., timber, oil and gas), and development (e.g., roads and power lines). These activities can potentially reduce the quality of northern aplomado falcon nesting, roosting, and foraging habitat, and may cause disturbance during the breeding season.

e. Conclusion Regarding Jeopardy

After reviewing the current status of the northern aplomado falcon, the environmental baseline for the action area, the effects from the use of Rozol, and the cumulative effects, it is the Service's biological opinion that the use of Rozol, as proposed, is not likely to jeopardize the continued existence of the northern aplomado falcon. No critical habitat has been designated for this species; therefore, none will be affected.

The reasons for this determination are:

- The northern aplomado falcon may prey on non-target organisms that feed on Rozol grain bait, but it is unlikely that this would occur regularly or predictably. Because the aplomado falcon does not feed upon dead animals, exposure to individuals would only occur from moribund animals on the surface. Moribund animals are expected to be a small proportion of Rozol-poisoned animals available on the surface.

- In areas where the northern aplomado falcon has been reestablished in Texas, landowners have signed cooperative agreements with the Service and The Peregrine Fund to maintain northern aplomado falcon habitat at or above baseline levels, and are responsible to notify these entities before performing land use practices that may adversely affect the northern aplomado falcon.
- As BTPD colonies are not known to be highly important habitat for northern aplomado falcon foraging, it is not anticipated that Rozol use as proposed in this action will preclude recovery of this species even when combined with other potential anthropogenic threats. In addition, cooperative agreements with landowners in reintroduction areas allows for the monitoring and potential avoidance of take within reintroduction areas.
- Most breeding aplomado falcons are outside the action area of this project in south Texas. This greater proportion is expected to persist for the duration of this project due to higher prey availability in the coastal region. Therefore, the survival of the northern aplomado falcon is not anticipated to be jeopardized by Rozol use in New Mexico and west Texas.
- Reintroduction of captively bred northern aplomado falcons is expected to continue within the range of the species during some years of this project.

INCIDENTAL TAKE STATEMENT

I. INTRODUCTION

Section 9 of the ESA and Federal regulation pursuant to Section 4(d) of the ESA prohibit the take of endangered and threatened species, respectively, without special exemption. *Take* means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture or collect, or to attempt to engage in any such conduct. *Harm* is further defined by the Service to include significant habitat modification or degradation that results in death or injury to listed species by significantly impairing essential behavioral patterns, including breeding, feeding, or sheltering. *Harass* is defined by the Service as intentional or negligent actions that create the likelihood of injury to listed species to such an extent as to significantly disrupt normal behavior patterns which include, but are not limited to, breeding, feeding or sheltering. *Incidental take* is defined as take that is incidental to, and not the purpose of, the carrying out of an otherwise lawful activity. Under the terms of Section 7(b)(4) and Section 7(o)(2), taking that is incidental to and not intended as part of the agency action is not considered to be prohibited taking under the ESA, provided that such taking is in compliance with the terms and conditions of the ITS.

The measures described below are non-discretionary and must be undertaken by the EPA so that they become binding conditions of any grant or permit issued to Liphatech, Inc., as appropriate, for the exemption in Section 7(o)(2) to apply. The EPA has a continuing duty to regulate the activity covered by this ITS. If the EPA 1) fails to assume and implement the terms and conditions, or 2) fails to require Liphatech, Inc. to adhere to the terms and conditions of the ITS through enforceable terms that are added to the permit document, the protective coverage of Section 7(o)(2) may lapse. In order to monitor the impact of incidental take, the EPA must report the progress of the action and its impact on the species to the Service as specified in the ITS (50 CFR § 402.14(i)(3)). For the northern aplomado falcon, this applies to Texas populations.

For northern aplomado falcons in New Mexico, the prohibitions against taking this species found in Section 9 of the ESA have been modified by the nonessential experimental designation. The results of this conference are advisory in nature and do not restrict agencies from carrying out, funding, or authorizing activities. However, the Service advises EPA to consider implementing the RPMs for northern aplomado falcons in New Mexico.

Under the Safe Harbor Agreement program, for northern aplomado falcons participating landowners are permitted to take aplomado falcons incidental to future lawful land-use actions (such as prairie dog control), provided that the landowner maintains any established baseline responsibilities (Service 2000b).
This ITS exempts take of black-footed ferrets, gray wolves, and northern aplomado falcons protected by the ESA that may be incurred by the proposed action, provided the September 10, 2010, Rozol label, with modifications specified herein, is followed.

Noncompliance with the Rozol label that results in take of gray wolves is not covered by this ITS; end users who do not comply with label requirements are not afforded take coverage and are subject to prosecution under Section 9 of the ESA.

II. AMOUNT OR EXTENT OF TAKE ANTICIPATED

A. Black-footed ferret

The Service has developed this ITS based on the premise that the EPA and Liphatech will implement the label measures that include black-footed ferret conservation measures as previously described. The conservation measures prohibit application of Rozol within current black-footed ferret reintroduction sites (12 sites in the 10 states) and future reintroduction areas to reduce the level of impact to the black-footed ferret. This information is to be located in the EPA's *Bulletin Live!* database. Changes to this database take approximately 8 months to enact; therefore, the Service will provide information to the EPA accordingly.

Take of black-footed ferrets is expected in the form of mortality when individuals disperse from a reintroduction area and encounter a BTPD colony that has been poisoned with Rozol within the previous 2 months, or if the black-footed ferret is residing on a colony when Rozol is applied. While black-footed ferrets can leave reintroduction sites, those departures are unlikely to be documented, and the Service is unable to accurately predict the number of black-footed ferrets that may encounter Rozol-poisoned BTPD colonies. Most black-footed ferrets that leave a reintroduction area are likely to die because of natural causes (predation/starvation) or other activities (vehicle collisions) unrelated to Rozol. Further, due to black-footed ferrets' nocturnal behavior and tendency to spend much of their time underground in prairie dog burrows, it is unlikely that many, if any, black-footed ferret mortalities due to Rozol will be reported to further inform this issue. Therefore, while dispersing black-footed ferrets may die from consuming Rozol-poisoned prairie dogs, this number is not anticipated to be large and will rarely be detected.

At previous black-footed ferret reintroduction sites, there are very few reports of dispersing animals outside the reintroduction site, and the reports received are typically associated with mortalities such as vehicle collisions or possible sightings that are followed up with concerted nighttime surveys (Hanebury and Biggins 2006). Black-footed ferret reintroduction site managers are authorized to retrieve dispersing black-footed ferrets if that information is available and if the landowner wants the black-footed ferrets removed from their property. Requests to relocate black-footed ferrets that have left a reintroduction area are very rare.

The Service anticipates that take of dispersing black-footed ferrets that leave a reintroduction area and encounter a Rozol poisoned BTPD colony will result in two or fewer black-footed ferret mortalities per year because the number of dispersing individuals is not believed to be high and most dispersing black-footed ferrets are expected to die of natural causes or other forms of incidental take. Black-footed ferrets that are captured alive from an area proposed for Rozol use and relocated to suitable habitat where Rozol will not be applied will not be counted against the lethal take of two black-footed ferrets per calendar year. The relocation of live black-footed ferrets from proposed Rozol use areas, while considered take, is authorized under each reintroduction sites' existing management plan and through a Service issued permit to the recovery partners at that site. That permit authorizes activities including black-footed ferret relocation, if needed, at each of the reintroduction sites through coordination with the Black-footed Ferret Recovery Coordinator. Therefore, this Rozol ITS is not intended to cover

relocation activities because such actions have been already been authorized under the ESA, or will be authorized by another means in the future. Black-footed ferret mortalities from those relocation efforts are not anticipated.

The Service does not anticipate take in the form of harm through habitat loss because the conservation measures prohibit Rozol use in existing and future black-footed ferret reintroduction sites. Current information does not indicate that Rozol use is limiting potential black-footed ferret reintroduction sites.

B. Gray wolf

The Service anticipates that dispersing wolves from source populations may occur in the BTPD range at an average rate of 0.65 wolves per year (essentially 1 or 2 every other year), based on documented mortalities outside of existing DPSs and the 10(j) area for the Mexican gray wolf. This is considered a conservative number as additional dispersers have likely occurred and have gone undetected. Other forms of mortality can affect these wolves before any exposure to Rozol occurs. However, if wolves ingest poisoned prey, evidence suggests that the wolves are likely to die. The exact number of wolves that may encounter a Rozol-poisoned prairie dog town with dead and dying prey is not determinable; however, we conclude that the number would be low. The Service anticipates that one ESA-protected gray wolf every 3 years could be taken as a result of this proposed action. Due to the long-distance dispersal capabilities of gray wolves, this take could conceivably occur in Rozol-poisoned prairie dog towns throughout the action area, but the risk is likely greatest in those states within proximity to the source populations of the recovered Northern Rocky Mountain and Western Great Lakes DPSs (e.g., North Dakota, South Dakota, Nebraska, and Colorado). Due to the low number of gray wolves in the Mexican gray wolf population, we anticipate take of gray wolves from the Mexican gray wolf to be lower. We anticipate that only one gray wolf from the Mexican gray wolf population will be taken over the course of the 15-year term of this biological opinion.

C. Northern aplomado falcon

Take of the northern aplomado falcon is expected in the form of mortality or sub-lethal effects such as changes in behavior when they consume prey from a BTPD colony that has been poisoned with Rozol. The Service is unlikely to know when that might occur nor be able to accurately predict the number of northern aplomado falcons that may encounter BTPD colonies or non-target prey that have been exposed to Rozol. It is unlikely that northern aplomado falcons will be found; therefore, it is unlikely that many, if any, northern aplomado falcon mortalities due to Rozol will be reported to further inform the EPA and the Service on this issue.

We anticipate that northern aplomado falcons in Texas that encounter Rozol-exposed BTPD colonies or non-target prey will result in one or fewer mortalities over 5 years. We further anticipate that one or fewer northern aplomado falcons in Texas over 5 years will be harassed to a level that results in take through a reduction in available nest sites caused by Rozol mortality to large raptors and ravens. However, since this take is unlikely to be easily detected, 2 falcon mortalities or injuries attributable to Rozol use will be considered to be representative of the total amount of take exempted for each 5 years of this 15-year project.

III. EFFECT OF TAKE

A. Black-footed ferret

The Service has determined that two mortalities per year of dispersing black-footed ferrets due to Rozol use is not likely to jeopardize the continued existence of the species or materially affect black-footed ferret recovery because individuals dispersing from reintroduction sites are not known to regularly return and contribute further to ferret recovery. It is acknowledged that if a Rozol-caused black-footed ferret mortality that is reported, there could be multiple black-footed ferret mortalities not found or reported. Because the expected mortalities are likely to be dispersing black-footed ferrets that are unlikely to contribute to the success of the reintroduction site, such losses are not anticipated to compromise the survival and recovery of the black-footed ferret.

B. Gray wolf

The Service determines that the level of anticipated take is not likely to result in jeopardy to the species or destruction or adverse modification of critical habitat. Gray wolf critical habitat does not occur within the action area. Few gray wolves are anticipated to disperse into the action area from established populations. The BTPD habitat is generally not preferred habitat for this species. Take is expected to be relatively low and not anticipated to have any population-level effects to recovered source populations of gray wolves that disperse into the action area. The low number of Mexican wolves (one over 15-year timeframe) that may be taken is not currently a threat to its recovery. Rozol use on BTPD towns, and any resulting take of gray wolves will likely not substantially change the mortality rates of long-distance dispersing wolves, as these individuals are already at high risk of encountering other known factors of wolf mortality during their travels. Rozol poisoning is likely a compensatory form of mortality (whereby any individuals lost to Rozol poisoning would have been likely to succumb to another form of mortality in the absence of Rozol) not resulting in an overall increase in total mortality of gray wolves.

C. Northern aplomado falcon

The Service has determined that two northern aplomado falcons, in the form of one mortality and one harassment per 5 years in the 15-year timeframe, due to Rozol use are not likely to jeopardize the continued existence of the northern aplomado falcon. This amount of take is not likely to result in population level effects to the species nor reduce its chances for recovery. This is due to the fact that the core of the northern aplomado falcon population is expected to persist at current or greater levels in southern Texas, outside the action area of this project. In addition, reintroduction of captively bred northern aplomado falcons is expected to continue within the range of the species during some years of this project.

IV. REASONABLE AND PRUDENT MEASURES

The Service believes the following RPMs are necessary and appropriate to minimize the impacts of incidental take of black-footed ferrets, gray wolves, and/or northern aplomado falcons resulting from the proposed action. The RPMs below apply to all three species unless specified otherwise within the RPM.

RPM 1:

- The EPA shall ensure that proper information regarding listed species and secondary poisoning risks is provided to Rozol users.

RPM 2:

- The EPA shall ensure that the best available information is applied to the Rozol label in the future.

RPM 3:

- The EPA, in cooperation with Liphatech, Inc. shall develop and maintain a system to track Rozol used for BTPD control and report to the Service the amounts distributed in each of the 10 States.

RPM 4:

- If an applicator or the EPA becomes aware that a black-footed ferret is known to occupy a BTPD colony outside of a reintroduction area, Rozol cannot be used on that colony until the individual or individuals have been relocated. The EPA will ensure that if a previously unknown wild black-footed ferret population is discovered, Rozol use will not be used on that population.

RPM 5:

- Within the range of the northern aplomado falcon, the EPA shall maintain its County Bulletin (*Bulletins Live!*) website so that a current listing of counties with habitat for northern aplomado falcons is available to the public for educational purposes. We are aware that an 8-month timeframe exists for incorporating any new information into *Bulletins Live!*.

RPM 6:

- Within the range of the northern aplomado falcon, the EPA shall inform public users about the risks of Rozol to non-target organisms and how risks can be minimized.

  The EPA has adopted Conservation Measures intended to reduce the adverse impacts of Rozol use on federally listed species via prohibition of Rozol use in some areas and/or timing restrictions; new Rozol label language requiring systematic search protocols to improve above-ground detection and disposal of above-ground target and non-target animals, reporting of federally listed species as well as reporting of any non-targets; and new education, training, and outreach efforts intended to improve applicator compliance with the Rozol label. The above RPMs with their implementing terms and conditions below include additional items not addressed by EPA's Conservation Measures. Some aspects of the education, training and outreach Conservation Measure requires additional coordination with

the Service to ensure content meets the intended purpose. Information regarding the most appropriate search protocol is currently lacking at this time, thus in the event improved methods are developed in the future, it is appropriate for EPA to consider that information and adjust the Rozol label accordingly to lower the risk of take. Information regarding the amount of Rozol produced, used, and sold is not currently available to the Service and constraints exist to obtaining it; thus gross production data will be evaluated over time as to whether it provides useful information relative to species' recovery prospects. Relocation of black-footed ferrets that have moved beyond reintroduction site boundaries and protection of currently unknown wild ferret population are appropriate steps to reduce take to that species. Education and outreach are deemed valuable to reduce the risk of take to northern aplomado falcons, particularly with the current level of ongoing coordination with private landowners.

V. TERMS AND CONDITIONS

Compliance with the following terms and conditions must be achieved in order to be exempt from the prohibitions of section 9 of the ESA. These terms and conditions implement the RPMs described above. These terms and conditions are nondiscretionary.

To implement RPM 1:

- The EPA shall submit to the Service, for review and approval prior to their use, materials to be used relative to the Conservation Measure for the EPA's additional training during annual pesticide applicator recertification programs and Liphatech's Rozol Prairie Dog Bait Product Stewardship Program. At a minimum, the training materials shall include (in addition to the information provided by EPA as a conservation measure) a description of the listed species and their habitats; the general provisions of the Endangered Species Act; the necessity for adhering to the provisions of the Act; the penalties associated with violating the provisions of the Act; the specific measures that are being implemented to use Rozol in a manner compatible with the conservation of listed species; and the boundaries in which Rozol can be lawfully applied.

- The EPA and Liphatech shall provide the Service with the opportunity to attend and participate in any education, outreach, and training sessions conducted as part of the EPA's efforts relative to the annual pesticide applicator recertification program and Liphatech's Rozol Prairie Dog Bait Product Stewardship Program.

To implement RPM 2:

- If information becomes available on more effective methods for search and removal protocols than the line-transect protocol specified on the label (as described in the Conservation Measures portion of the Description of the Proposed Action section above), the EPA shall incorporate the best available information on the Rozol label to reduce the availability of Rozol-poisoned target and non-target animals on the surface after coordinating with the Service.

To implement RPM 3:

- Liphatech and the EPA will provide information to the FWS regarding the amount of Rozol produced for BTPD control and the gross distribution per state for a period of 5 years. When Liphatech and the EPA provide such information to FWS, it will be marked, if appropriate, as Confidential Business or Commercial Information. After 5 years, the EPA, Liphatech and the Service will determine the need for continued reporting. The decision of whether to continue this reporting will be based upon the confidence that the available information provides the Service with an acceptable understanding of Rozol sales for future projection over the course of the Biological Opinion for the registration of Rozol. The factors that may be considered shall include (but shall not be limited to):

    - Measures of the statistical confidence in the sales trend derived from the 5 years of reported data, and

    - The nature of the trend function fitted to the available sales data.

      For example, if the data suggest that the sales trend has reached some asymptote, the continuation of additional reporting may be unnecessary as the market has matured (other factors may be considered in this event). If the sales trend shows a logarithmic increase in sales, there may be a need to continue reporting to determine if this trend estimate is accurate. If the trend line shows a stable linear growth, the registrant my elect to terminate or continue reporting with the understanding that the trend line information up to that point would serve as the predictor of sales and treated acres for the remainder of the registration decision.

To implement RPM 4:

- In the event live/dead black-footed ferrets are found outside reintroduction sites, before, during, or after Rozol application, the Black-footed Ferret Coordinator must be contacted immediately at (970) 897-2730, extension 224. Sufficient time must be allowed to capture and relocate black-footed ferrets before Rozol application. Additional contact information for the Black-footed Ferret Coordinator is provided below under "*Disposition of federally listed species.*"

- The EPA shall modify the EPA *Bulletins Live!* website to include the location of wild extant black-footed ferret populations if discovered in the future.

To implement RPM 5:

- By November 26, 2012, within the range of the northern aplomado falcon, the EPA shall include the following language in the EPA's County Bulletins (*Bulletins Live!*) for counties with falcon habitat to increase landowner awareness in these areas:

  Prairie dog colonies in this county may be occupied by the federally endangered northern aplomado falcon. Rozol application may be harmful to the northern aplomado falcon. Please contact the U.S. Fish and Wildlife Service in New Mexico at 505-346-2525, and in Texas at 817-277-1100 to find out where northern aplomado falcons occur in the county before application.

To implement RPM 6:

- Prior to Rozol application in the range of the falcon, the EPA will include content on its Endangered Species Protection Program (ESPP) website about the risks of Rozol to non-target organisms, such as the aplomado falcon and its prey, and how risks can be minimized. This information will be developed in coordination with the Service, and will be in a format that can be printed as a hand-out for distribution to landowners with suitable habitat for the northern aplomado falcon.

- This information will also be electronically provided to states that include the northern aplomado falcon range for their use and dissemination during certified applicator training.

Reporting Requirement

When incidental take is anticipated, provisions for monitoring activities of the action are required to determine actual effects on federally listed species. Monitoring and reporting is essential for the Service to assess the action effects, track incidental take levels, and refine the BO, RPMs, and terms and conditions. Thus, the EPA shall provide a written annual report to the Service each year this biological opinion is in effect. The report shall be submitted to the Service by May 15 of each year. The report shall include:

- The number of, and species of, any non-target species reported to the National Pesticide Information Center, with associated relevant incident information;

- The number and locations of applicator training sessions, including the number of attendees at each training.

- The number and circumstances surrounding any federally listed species killed or injured as a result of Rozol poisoning;

- A discussion of progress in implementing the RPMs and terms and conditions contained in the BO, including:

    - Any problems encountered in implementing them;

    - Recommendations for modifying the stipulations to enhance the conservation of the covered species;

    - Any new information, study results, or other relevant information that EPA receives regarding the proposed action and it's likely effects to listed species;

    - A description of activities planned for the coming reporting year; and

    - Any other pertinent information.

This document will assist the Service, the EPA, and the Liphatech evaluating future measures for the conservation of the black-footed ferret, gray wolf, and aplomado falcon.

Disposition of Dead or Injured Federally Listed Species

Upon locating dead, injured, or sick federally listed species, the animals shall be left in place, photographed if possible, and immediately reported to one of the Service Law Enforcement numbers provided on the label (via EPA's Conservation Measure to change the label), or a local Service Law Enforcement Agent, along with any information related to Rozol use in the area where the animals were found. The date, time, location, and any other relevant details shall be conveyed. Specimens (collected by authorized individuals) shall be kept cool or frozen to facilitate later examination for Rozol poisoning. Sick or injured animals shall be picked up and transported by authorized individuals to a permitted local wildlife rehabilitation or veterinary facility for treatment. Care must be taken in handling sick or injured animals to ensure effective treatment.

For federally listed species located in the States of Montana, North Dakota, South Dakota, Wyoming, Nebraska, Colorado and Kansas, the local Service Ecological Services Office within the state the animal is detected shall be notified as soon as possible and informed of the incident and local Rozol use, if known. Office contact information may be found on the internet at www.fws.gov.

The National Black-Footed Ferret Coordinator must also be notified at U.S. Fish and Wildlife Service, P.O. Box 190, Wellington, CO 80549. Phone: 970-897-2730 x 224, Fax: 970-897-2943 Mobile: 720-626-5260.

For gray wolves located in Oklahoma, New Mexico, or Texas (potentially Mexican gray wolves from a reintroduced population) the Mexican Wolf Recovery Coordinator must be notified as soon as possible and informed of any Rozol use, if known. Contact: U.S. Fish and Wildlife Service, New Mexico Ecological Services Field Office, 2105 Osuna Road NE, Albuquerque, NM 87113, Office Phone: (505) 761-4748, Office Fax: (505) 346-2542.

The Service's Northern Aplomado Falcon Coordinator must also be notified of sick, injured, or dead northern aplomado falcons within 24 hours by calling (505) 346-2525 at the New Mexico Ecological Services Field Office, 2105 Osuna Road NE, Albuquerque, NM 87113; Fax: (505) 346-2542.

The Service believes that no more than two black-footed ferrets per year; one wolf every 3 years with only one being from the Mexican wolf population; and two northern aplomado falcons for each 5-year period within this 15-year project will be incidentally taken as a result of the proposed action. The Service expects that the RPMs, with their implementing terms and conditions, are designed to minimize the impact of incidental take that might otherwise result from the proposed action. If, during the course of the action, this level of incidental take is exceeded, such incidental take represents new information requiring reinitiation of consultation and review of the RPM provided. The EPA must immediately provide an explanation of the causes of the taking and review with the Service the need for possible modification of the RPM.

VI. CONSERVATION RECOMMENDATIONS

Section 7(a)(1) of the ESA directs Federal agencies to use their existing authorities to further the purposes of the ESA by carrying out programs or activities to conserve endangered or threatened species. Conservation recommendations are discretionary activities to minimize or avoid adverse effects of a proposed action on listed species or critical habitat, to help implement recovery plans, or to develop biological information. The Service recommends the following conservation activities that are within the EPA's authorities and can benefit northern aplomado falcon recovery. We believe implementation of these will assist EPA in demonstrating that it is meeting the requirements of 7(a)(1) of the ESA.

- A voluntary reporting form shall be developed and made available at training or education sessions and on the internet in association with Rozol information that identifies the time and date of return visits, which wildlife species were located, disposition of wildlife found (i.e., whether the prairie dogs were removed from the colony, if Rozol was found on the surface and other information that can be used to assess the routes of exposure to nontarget wildlife). Completed forms shall be sent directly to the Service.

- The EPA should work in coordination with the Service to evaluate methods to prevent secondary poisoning of federally listed species by performing a field study that allows for an evaluation of efficacy of the newly implemented line-transect animal search and removal protocol as well as other feasible methods to prevent secondary poisoning. Although other research entities may be acceptable, the Service recommends the EPA contact a university to develop a graduate-level research study with the objective of determining appropriate search methodology/protocols to reduce the above-ground availability of Rozol-poisoned BTPDs and non-target animals.

- The EPA should become a member of the Black-footed Ferret Recovery Implementation Team due to its congressionally delegated responsibilities for regulating rodenticides and recovering federally threatened and endangered species. Prairie dog rodenticide registrations under FIFRA are significant actions that can adversely affect black-footed ferrets and other listed species. The EPA participation on the Black-footed Ferret Recovery Implementation Team would provide an avenue for the agency to understand the ramifications of rodenticide use on black-footed ferret habitat along with an opportunity to work with recovery partners to ensure EPA actions avoid working at cross purposes with black-footed ferret recovery.

- The EPA should monitor the registered rodenticides used on the three species of prairie d in the black-footed ferrets' range and report the amounts of prairie dog rodenticides sold used, and the expected prairie dog acreage poisoned per state per year.

- The EPA should initiate or require studies to evaluate secondary toxicity of the EP registered prairie dog rodenticides to black-footed ferrets.

- The EPA should implement the above listed RPMs and Terms and Conditio nonessential experimental range of the northern aplomado falcon i Rozol may be used.

- The EPA should coordinate with the New Mexico Ecological Services Field Office to assist in recovery efforts for the northern aplomado falcon by contributing to research, monitoring, and/or falcon reintroductions.

- The EPA should initiate or require studies to evaluate secondary toxicity of the EPA registered prairie dog rodenticides to northern aplomado falcons, other raptors, and ravens.

In order for the Service to be kept informed of actions minimizing or avoiding adverse effects or benefiting listed species or their habitats, the Service requests notification of the implementation of any conservation recommendations.

VII. REINITIATION NOTICE

This concludes formal consultation on the action outlined in the EPA's September 30, 2010, request for formal consultation regarding federally listed species and critical habitat impacts relative to the registration and application of Rozol to control BTPDs in 10 western States. As provided in 50 CFR § 402.16, reinitiation of formal consultation is required where discretionary Federal agency involvement or control over the action has been retained (or is authorized by law) and if: 1) the amount or extent of incidental take is exceeded (or take occurs of species for which the Service currently does not anticipate adverse effects from the proposed action); 2) new information reveals effects of the agency action that may impact listed species or critical habitat in a manner or extent not considered in this BO (for example, this BO does not cover Rozol use on any other prairie dog species; thus, expansion of Rozol use to prairie dog species other than the BTPD would necessitate reinitiation of formal consultation; changes to the September 10, 2010, Rozol label altering the application of the product may also represent new information not considered herein); 3) the agency action is subsequently modified in a manner that causes an effect to the listed species or critical habitat that was not considered in this BO; 4) future information indicates that Rozol use by itself or in combination with other factors is precluding black-footed ferret recovery, then the EPA and the Service shall reinitiate consultation to determine appropriate measures to allow black-footed ferret recovery to proceed; or 5) a new species is listed or critical habitat is designated that may be affected by the action. In instances where the amount or extent of incidental take is exceeded, any activities causing such take must cease pending reinitiation.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES,
AND TOXIC SUBSTANCES

August 24, 2012

Thomas Schmit
Liphatech, Inc.
3600 West Elm Street
Milwaukee, WI 53209

Dear Mr. Schmit:

Subject: (1) Amended labeling to add mechanical application
(2) Supplemental label for mechanical application
Rozol® Prairie Dog Bait
EPA Registration No. 7173-286

The proposed labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable.

As a condition of registration you must submit within 30 days from the date of this letter requests for voluntary cancellation of any Special Local Need registrations for Rozol Prairie Dog Bait. Submit the requests to both EPA and the affected states.

Stamped copies are enclosed for your records. Please submit one copy of your final printed labeling before you release the product for shipment. Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). If you have any questions, please contact me by phone at: (703) 308-6249, or by email at: hebert.john@epa.gov.

Regards,

John Hebert, PM 7
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

RESTRICTED USE PESTICIDE
DUE TO HAZARD TO NONTARGET ORGANISMS
For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certificate.

ROZOL®
PRAIRIE DOG BAIT

Active Ingredient: chlorophacinone	0.005%
Inert Ingredients	99.995%
Total	100.000%

EPA Reg. No. 7173-286 EPA Est. No. 7173-WI-1

KEEP OUT OF REACH OF CHILDREN

CAUTION: See side panel for additional precautionary statements.

(Liphatech Logo)
Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209
(414) 351-1476

Net Weight: 1 pound up to 2000 pounds

WARRANTY: To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of product when such use and/or handling is contrary to label instructions.

Side Panel:

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

CAUTION: Harmful if swallowed or absorbed through the skin because it may reduce the clotting ability of blood and cause bleeding. Keep away from children, domestic animals and pets. Do not get in eyes on skin or on clothing. All handlers (including applicators) must wear shoes plus socks, and gloves. Any person who retrieves carcasses or unused bait following application of this product must wear gloves.

USER SAFETY REQUIREMENTS: Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands thoroughly after applying bait and before eating, drinking, chewing gum, using tobacco or using the toilet and change into clean clothing.

FIRST AID: Have label when obtaining treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor.

If on skin: Take off contaminated clothing. Rinse skin with plenty of cool water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

TREATMENT FOR PET POISONING: If animal eats bait, call veterinarian at once.

NOTE TO PHYSICIAN OR VETERINARIAN: Contains chlorophacinone, an anticoagulant. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. For humans or dogs that have ingested this product and/or have obvious poisoning symptoms (bleeding or prolonged prothrombin times), give Vitamin K_1 intramuscularly or orally.

ENVIRONMENTAL HAZARDS: This product is toxic to fish and wildlife. Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten this bait. Do not apply directly to water, or to areas where surface water is present. Do not contaminate water by cleaning of equipment or disposal of wastes. Runoff also may be hazardous to aquatic organisms in water adjacent to treated areas.

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in a cool, dry place inaccessible to children and pets.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of in trash or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. **[Plastic:]** Completely empty container, then offer for recycling or reconditioning; or puncture and dispose of in a sanitary landfill. **[Paper:]** Completely empty container, then dispose of empty container in trash or at an approved waste disposal facility.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL and follow all use directions and precautions. Only use for sites, pests, and application methods specified on this label.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Dispose of product container, unused, spoiled and unconsumed bait as specified on this label.

Use restrictions: This product may only be used as follows:

1. **Sites/Pests:** Black-Tailed Prairie Dogs (*Cynomys ludovicianus*) on rangeland and adjacent noncrop areas.
2. **States:** Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas and Wyoming. Do not apply this product within the exterior boundaries of the Crow Reservation or the Blackfeet Reservation in Montana.

3. **Application Method:** Apply bait by hand scoop or a mechanical bait application machine that is designed, constructed and operated in a manner that ensures that bait is properly placed at least 6 inches down the prairie dog burrows. This product may only be used in underground applications. Do not apply bait on or above ground level. Treat only active burrows.
4. **Treatment Period:** Apply between October 1 and March 15 of the following year, when animals will most readily take the grain bait.
5. **Non-Applicators:** Do not allow children, pets, domestic animals or persons not involved in the application to be in the area where the product is being applied.
6. **Grazing Restriction:** Do not allow livestock to graze in treated areas for 14 days after treatment and when no bait is found above ground.
7. Do not use any other rodenticides containing anticoagulants (diphacinone) in prairie dog towns during the treatment period allowed on this label.

Endangered Species: It is a Federal offense to use any pesticide in a manner that results in the death of an endangered species. Use of this product may pose a hazard to endangered or threatened species. When using this product, you must follow the measures contained in the Endangered Species Protection Bulletin for the county in which you are applying the product. To obtain Bulletins, no more than six months before using this product, consult http://www.epa.gov/espp/ or call 1-800-447-3813. You must use the Bulletin valid for the month in which you will apply the product.

Site Assessment: Before applying this product, identify active prairie dog burrows by visual observation. The openings of active burrows will generally be free of leaves, seeds, other debris or spider webs, and will show freshly turned earth, and have prairie dog feces nearby.

Application: Apply 1/4 cup (53 grams or nearly 2 ounces) of bait at least 6 inches down active prairie dog burrows. Make sure no bait is left on the soil surface at the time of application. Applicator must retrieve and dispose of any bait that is spilled above ground or placed less than 6 inches down the burrow entrance.

Follow-up: Prairie dogs that have eaten this bait will begin to die off 4 to 5 days after they eat a lethal amount. The applicator must return to the site within 4 days after bait application, and at 1 to 2 day intervals, to collect and properly dispose of any bait or dead or dying prairie dogs found on the surface. Carcass searches must be performed using a line-transect method that completely covers the baited area. Transect center lines must be not more than 200 feet (about 60 meters) apart, and should be considerably less if searches are conducted in more densely vegetated sites. Transect lines may be traveled on foot or by vehicle at a rate not to exceed 4 mph. All carcasses found above ground must be collected and disposed of properly. Continue to collect and dispose of dead or dying prairie dogs and search for non-target animals for at least two weeks, but longer if carcasses are still being found at that time. Carcass collection should occur in late afternoon, near sundown, to reduce the potential of nocturnal animals finding carcasses and dying animals. Bury carcasses on site in holes dug at least 18 inches deep or in inactive burrows (no longer being used by prairie dogs or other species) to avoid non-target animal scavenging. Burial includes covering and packing the hole or burrow with soil. If burial is not practical (due to frozen ground, etc.) and other disposal methods are allowed by state and local authorities, collected carcasses may be disposed of by other methods to insure that the carcasses are inaccessible to scavengers.

All dead or dying non-target animals must be reported to the National Pesticide Information Center 1-800-858-7378 as soon as possible. Any apparently injured or sick Federally listed species must also be immediately reported by calling 303-236-7540 (if located in Kansas, Nebraska, the Dakotas, Montana, Colorado or Wyoming) or 505-248-7889 (if located in Texas, New Mexico or Oklahoma). The Black-footed Ferret Coordinator must also be contacted if ferrets are found during Rozol Prairie Dog Bait applications or carcass searches at 970-897-2730 x224. If live black footed ferrets are found outside reintroduction sites, before, during or after Rozol Prairie Dog Bait application, the Black-footed Ferret Coordinator must be contacted immediately and sufficient time must be allowed for the FWS to capture and relocate the black-footed ferret(s) before Rozol Prairie Dog Bait application.

Reapplication: If prairie dog activity persists several weeks or months after the bait was applied, a second application may be made, by treating burrows in the same manner, time period and procedure as the first application. Follow all application, site assessment and follow-up directions and use restrictions as found above.

RESTRICTED USE PESTICIDE

DUE TO POTENTIAL SECONDARY TOXICITY TO NONTARGET ORGANISMS

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

SUPPLEMENTAL LABELING

rozol®

PRAIRIE DOG BAIT

ACCEPTED
AUG 24 2012
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide Registered under EPA Reg. No. 7173-286

SUPPLEMENTAL LABELING WITH DIRECTIONS FOR APPLICATION BY MECHANICAL BAIT PLACEMENT MACHINE

Active Ingredient: chlorophacinone	0.005%
Inert Ingredients	99.995%
Total	100.000%

EPA Reg. No. 7173-286
EPA Est No. 7173-WI-1

KEEP OUT OF REACH OF CHILDREN

CAUTION: See label on or attached to the pesticide container for additional precautionary statements.

This label valid until March 15, 2014, and must not be used or distributed after that date.

All applicable directions, restrictions and precautions on the EPA registered label are to be followed. Before using Rozol Prairie Dog Bait as permitted according to this Supplemental Labeling, read and follow all applicable directions, restrictions and precautions on the EPA registered label on or attached to the pesticide container. This Supplemental Labeling contains revised use instructions and/or label restrictions that may be different from those that appear on the container label. This Supplemental Labeling must be in the possession of the user at the time of pesticide application.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Use restrictions: This product may only be used in underground applications to control black-tailed prairie dogs (*Cynomys ludovicianus*) on rangeland and noncrop areas. Apply between October 1 and March 15 of the following year, when animals will most readily take the grain bait. This product is toxic to nontarget wildlife and fish. Do not allow bait to be placed outside of the prairie dog burrow. Do not allow children, pets, domestic animals or persons not involved in the application to be in the area where the product is being applied. Do not allow livestock to graze in treated areas for 14 days after treatment and when no bait is found above ground. Before applying this product, identify active prairie dog burrows by visual observation. The openings of active burrows will generally be free of leaves, seeds, other debris or spider webs, and will show freshly turned earth, and have prairie dog feces nearby.

Application: Apply 1/4 cup (53 grams or nearly 2 ounces) of bait at least 6 inches down active prairie dog burrows. Application may be made with a mechanical bait application machine that is designed, constructed and operated in a manner that ensures that bait is properly placed at least 6 inches down the prairie dog burrows. **Make sure no bait is left on the soil surface at the time of application.** Applicator must retrieve and dispose of any bait that is spilled above ground or placed less than 6 inches down the burrow entrance. Mechanical bait application machines must be calibrated to ensure that the proper amount of bait is dispensed into each prairie dog burrow.

Follow-up: The applicator must return to the site within 4 days after bait application, and at 1 to 2 day intervals, to collect and properly dispose of any bait or dead or dying prairie dogs found on the surface. The applicator must follow all label instuctions for conducting carcass searches, proper disposal of carcasses, and reapplication. (081712)

LIPHATECH®

Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209
(800) 351-1476

ROUTING AND TRANSMITTAL SLIP	Date: 05/24/12	
TO: *(Name, office symbol, room number, building, Agency/Post)*		
1. Mark Corbin	MC	5/24/12
2. Marty Monell		
3.		
4.		
5.		

	Action		File		Note and Return
XX	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate	XX	Signature
	Coordination		Justify		

REMARKS

Renegotiation of PRIA date from 05/24/12 to 07/24/12. Registrant has agreed to this date via email.

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions.

FROM: *(Name, org. symbol, Agency/Post)*	Room No.– Bldg. : S-7227
John Hebert Office of Pesticide Programs Registration Division	Phone No. 308-6249

Recommendation of Division Directors
Negotiated Due Dates

Decision #: 442642	Registration #: 7173-286	Petition #:

☐ *See page 2 for additional registration entries*

Chemical Name: Chlorophacinone

Fee Category: R350		**PRIA Decision Time Frame:** 8 Months	
Submitted by: John	Hebert	**Branch:** OCSPP/OPP/RD	**Date:** 05/24/2012

Company: Liphatech

Original PRIA Due Date: 09/24/2011	**Proposed New PRIA Due Date:** 07/24/2012

Previous Negotiated Due Dates: 05/24/2012

Is the "Fix" in-house? ☐ Yes ☐ No ☑ n/a **If not, date "Fix" expected:**

Negotiated Due Date Reason:

Additional Data Required	☐ Product Chemistry	☐ Toxicology	☐ Acute Tox	☐ Environmental	
	☐ Efficacy	☐ Ecological	☐ Residue	☐ Other	
Data Deficiencies	☐ Product Chemistry	☐ Acute Tox	☐ Efficacy	☐ Residue	☐ Toxicology
	☐ Environmental	☐ Ecological	☐ Labeling	☐ Other	☐ Not Submitted
Late Risk Assessment	☐ Human Health	☐ Ecological			
Interim Consideration	☐ Agency Initiated	☐ Registrant Initiated			

☐ CSF	☐ Public Process	☐ Risk Issues Environmental	☐ Risk Issues Human Health
☐ Impurities Review	☐ Label	☐ Administrative-FR Notice	☑ Other – Comment Field

Summary of Deficiency Type(s): ☐ **Not Submitted (N)** ☐ **Deficiencies (D)**

Product Chemistry: ☐ **Acute Tox:** ☐ **Efficacy:** ☐ **Labeling:** ☐ **Ecological Data:** ☐ **Other (describe):** ☑

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

The registrant, Liphatech was conctacted via Email and agreed to both negotiated due dates. A 75 day letter was not written because this is not a deficiency on the registrant's part.

"75 Day" Letter sent? ☐ **Yes, Date sent** ☑ **No and reason for none?** *Add comments on page 2*

Rationale for Proposed Due Date: The proposed time can allow for interaction with FWS.

Registrant notified that this is the last negotiation? ☐ **Yes** ☑ **Not Applicable**

Approve: ☒ **Disapprove:** ☐

If disapproved, action to be taken:

OD or DOD Signature: William Jordan **Date:** May 24, 2012

Decision #:	Registration #:	Petition #:

Issue(s) (describe in detail):

Amendment is to add mechanical application to labeling. It is not clear if we need to involve FWS and/or do a Notice of Receipt to approve this action. The additional time is needed if this is necessary.

Comment(s):

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv4a.pdf
Form Number: PRIA
Document Identifier: PRIA-12145145452-GB

SUBMITTED on 05/24/2012 at 03:20:02 PM by CN=Gene Benbow/OU=DC/O=USEPA/C=US

Recommendation of Division Directors
Negotiated Due Dates

Decision #: 442642	Registration #: 7173-286	Petition #:

☐ *See page 2 for additional registration entries*

Chemical Name: Chlorophacinone

Fee Category: R350 | **PRIA Decision Time Frame:** 8 months

Submitted by: Dan Peacock | **Branch:** OCSPP/OPP/RD | **Date:** 09/19/2011

Company: Liphatech, Inc., Milwaukee, WI

Original PRIA Due Date: 09/24/2011 | **Proposed New PRIA Due Date:** 05/24/2011

Previous Negotiated Due Dates:

Is the "Fix" in-house? ☑ Yes ☐ No ☐ n/a | **If not, date "Fix" expected:**

Negotiated Due Date Reason:

Additional Data Required	☐ Product Chemistry	☐ Toxicology	☐ Acute Tox	☐ Environmental	
	☐ Efficacy	☐ Ecological	☐ Residue	☐ Other	
Data Deficiencies	☐ Product Chemistry	☐ Acute Tox	☐ Efficacy	☐ Residue	☐ Toxicology
	☐ Environmental	☐ Ecological	☐ Labeling	☐ Other	☐ Not Submitted
Late Risk Assessment	☐ Human Health	☐ Ecological			
Interim Consideration	☐ Agency Initiated	☐ Registrant Initiated			

☐ CSF	☐ Public Process	☑ Risk Issues Environmental	☐ Risk Issues Human Health
☐ Impurities Review	☐ Label	☐ Administrative-FR Notice	☐ Other – Comment Field

Summary of Deficiency Type(s): ☐ Not Submitted (N) ☐ Deficiencies (D)

Product Chemistry: ☐ **Acute Tox:** ☐ **Efficacy:** ☐ **Labeling:** ☐ **Ecological Data:** ☐ **Other (describe):** ☑

This product is the subject of a July 27, 2011 court order and ongoing consultations that prevent the Agency from approving any pending amendments.

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

IRB contacted the company representative, Mr. Tom Schmit, on September 15, 2011, providing the options of withdrawal or renegotiating the due date for an additional 8 months, or May 24, 2012. On September 16, 2011, Mr. Schmit agreed to renegotiate the due date until March 24, 2012.

"75 Day" Letter sent? ☐ **Yes, Date sent** ☐ **No and reason for none?** *Add comments on page 2*

Rationale for Proposed Due Date:

Registrant notified that this is the last negotiation? ☐ Yes ☑ Not Applicable

Approve: ☑ | **Disapprove:** ☐

If disapproved, action to be taken:

OD or DOD Signature: *CN=Marty Monell/OU=DC/O=USEPA/C=US* | **Date:** *09/29/2011*

Decision #: 442642	Registration #:7173-286	Petition #:

Issue(s) (describe in detail):

Purpose:
The company is seeking an amendment to add a method of application (mechanical) not approved at the initial product registration in May 2009.

Court Case:
This product contains the anticoagulant, Chlorophacinone, for the control of prairie dogs.
Shortly after registration, Defenders of Wildlife and Kansas Audubon sued the EPA for registering this rodenticide because of high ecological risks, because of failure to pubish the new use for public comment [resulting in OPP's now publishing Notices of Receipt of all new ues and developing its Public Process for significant new uses], and because we had not consulted with Fish and Wildlife Service about Endangered Species.

On July 27, 2011, EPA received a court order, requiring us to remove specific states of use from the label and to consult with the Fish and Wildlife Service. In the interim, the Agency cannot act on any amendments for this product until it has completed the consultation.

Bottomline:
The Agency estimates that it will need an additional 8 months, or May 24, 2012, to comply with the July 27, 2011, court order and consider this amendment for a new label change.

Comment(s):

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv4a.pdf
Form Number: PRIA
Document Identifier: PRIA-11262081025-DP

SUBMITTED on 09/19/2011 at 10:08:55 AM by CN=Dan Peacock/OU=DC/O=USEPA/C=US

TAKEN BACK on 09/19/2011 at 01:14:27 PM by CN=Dan Peacock/OU=DC/O=USEPA/C=US

SUBMITTED on 09/19/2011 at 01:43:09 PM by CN=Dan Peacock/OU=DC/O=USEPA/C=US

APPROVED on 09/19/2011 at 03:19:33 PM by CN=Meredith Laws/OU=DC/O=USEPA/C=US

TAKEN BACK on 09/21/2011 at 12:07:30 PM by CN=Dan Peacock/OU=DC/O=USEPA/C=US

SUBMITTED on 09/21/2011 at 12:10:29 PM by CN=Dan Peacock/OU=DC/O=USEPA/C=US

APPROVED on 09/21/2011 at 12:12:56 PM by CN=Meredith Laws/OU=DC/O=USEPA/C=US

APPROVED on 09/21/2011 at 12:29:20 PM by CN=Dan Rosenblatt/OU=DC/O=USEPA/C=US

REROUTED on 09/29/2011 at 03:36:46 PM by CN=Elizabeth Leovey/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 09/29/2011 at 04:12:16 PM by CN=Marty Monell/OU=DC/O=USEPA/C=US

Fw: PRIA action for 7173-286
Meredith Laws to: Dan Peacock 09/16/2011 09:38 AM
Cc: John Hebert

History: This message has been replied to.

Dan - Liphatech has agreed to renegotiateD442642. See below.

Please prepare the webform renegotiation and send it forward by Tuesday.

---- Forwarded by Meredith Laws/DC/USEPA/US on 09/16/2011 09:35 AM ----

From: Thomas Schmit <SchmitT@liphatech.com>
To: Meredith Laws/DC/USEPA/US@EPA
Cc: Al Smith <SmithA@liphatech.com>, Chuck Hathaway <HathawayC@liphatech.com>, Carl Tanner <TannerC@liphatech.com>
Date: 09/16/2011 09:26 AM
Subject: RE: PRIA action for 7173-286

Dear Ms. Laws -

We agree to move the PRIA due date for this amendment action out another 8 months, to May 24, 2012.

Thanks -
Thomas Schmit
Liphatech, Inc.

-----Original Message-----
From: Laws.Meredith@epamail.epa.gov [mailto:Laws.Meredith@epamail.epa.gov]
Sent: Thursday, September 15, 2011 3:13 PM
To: Thomas Schmit
Subject: PRIA action for 7173-286

Tom:

You submitted a PRIA action to add mechanical application to the section 3 label for EPA Reg. No. 7173-286. The PRIA due date is Sept. 24, 2011.

Based on the July 27, 2011 court order and the ongoing consultation, we are not going to approve this label change. You may withdraw the action (and receive a refund of a portion of the PRIA fee), or renegotiate the due date. We would want an additional 8 months (so a new date of May 24, 2012) if you decide to renegotiate.

Meredith

LIPHATECH

3600 WEST ELM STREET
MILWAUKEE, WI 53209
Tel: 414/351 1476 800/351 1476
Fax: 414/247 8166

Document Processing Desk (REGFEE)
EPA Office of Pesticide Programs (7504P)
One Potomac Yard, Room S4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Mr. John Hebert, Insecticide/Rodenticide Branch

November 24, 2010

Re: Application for amended registration of
Rozol Prairie Dog Bait, EPA Reg. No. 7173-286

Dear Mr. Hebert,

The enclosed application package is submitted in order to modify the label of an existing rodenticide product registration. While we believe that this action is a fast track amendment, we are voluntarily submitting this as an R340 amendment and paying the associated fee, in order that this action will have a defined timeline under PRIA. A copy of the payment receipt is attached.

The current approved label for Rozol Prairie Dog Bait (date-stamped September 10, 2010) contains a requirement for "hand application:"

> "3. Application method: **Hand application** of bait, at least 6 inches down prairie dog burrows." (emphasis added)

This restriction was never present on any of the six SLN label for prairie dog bait that existed prior to issuance of 7173-286. This restriction was not included on the label that Liphatech submitted with our application to register this product, and we have never received an explanation of why it was added. The data we submitted in support of this product included applications made with mechanical application devices. We attempted to get this language changed shortly after the registration was issued, but were told that no changes would be made during EPA's consideration of petitions to suspend this registration (electronic docket EPA-HQ-OPP-2009-0684). EPA has now formally concluded this consideration.

The proposed label submitted today contains one single specific change: it removes this requirement for "hand application," and would thus allow for the proper placement of bait by hand or by mechanical application equipment:

Bait application by mechanical equipment has already been considered in the risk assessments conducted by EPA's Environmental Fate and Effects Division (EFED). In their "Risks of Chlorophacinone Use on Black Tailed Prairie Dogs to Federally Endangered and Threated Species" document dated September 29, 2010 (identified on EPA's website as "Chlorophacinone Effects Determination"), EFED specifically discusses the issues of bait

LiphaTech Home Page: http//www.liphatech.com
E-mail: rodentcontrol@liphatech.com

exposure at application sites (pages 60-63 of the cited document). This exposure assessment examined the amount of bait available on the surface of the ground based on the data from MRID 47333602. This MRID is assigned to the large-scale field study "Field Efficacy and Hazards of Rozol Bait for Controlling Black-Tailed Prairie Dogs" by Hygnstrom and Lee, 2007, which was sponsored and submitted by Liphatech in support of this registration.

In this study, 10 separate experimental plots were treated (totaling 11,479 burrows covering 144 acres), four of which were treated by hand bait placement only. Of the remaining six plots, three were treated with the use of mechanical bait applicators only (1926 burrow on 22.6 acres), and three were treated using both hand application and mechanical bait applicators (3274 burrows on 43 acres). The EFED exposure analysis of bait availability on the ground surface was conducted using the data from this study, and no other studies or data are cited in the analysis. Therefore, this EFED analysis included any possible effects that could be attributed to the use of mechanical application equipment.

As such, there should be no need for any further review or ecological risk assessment due to this proposed label change. Now that EPA has officially concluded its consideration of petitions to suspend the registration of Rozol Prairie Dog Bait, there should be no obstacle to the timely processing of this amendment.

Thank you for your attention to this matter. Please contact me directly if there is any problem or question concerning this submission.

Sincerely,

Thomas Schmit
Manager of Regulatory Affairs

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
7173-286	John Hebert	☐ None ☒ Restricted
4. Company/Product (Name) Rozol Prairie Dog Bait	**PM#** Insecticide/Rodenticide Branch	

5. Name and Address of Applicant *(Include ZIP Code)*

Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☒ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

The enclosed application package is submitted in order to amend the product label as described in the cover letter dated November 24, 2010. We believe that this action is a fast track amendment, but we are voluntarily submitting it as an R340 amendment and paying the fee of $3617, in order that this action will have a defined timeline under PRIA. A copy of the payment receipt is attached. Please contact Thomas Schmit at 414-410-7230, or schmitt@liphatech.com with any questions or concerns.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☒ Plastic ☐ Glass ☒ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container	1 pound up to 2000 pounds	✓ On label

6. Manner in Which Label Is Affixed to Product ☒ Lithograph ☒ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas Schmit	Manager of Regulatory Affairs	(414) 410-7230

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
	Manager of Regulatory Affairs	Thomas Schmit	November 24, 2010

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Online Payment

Step 3: Confirm Payment **1 | 2 | 3**

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 251VGV3B
Agency Tracking ID: 74154802285
Transaction Date and Time: 11/24/2010 12:54 EST

Payment Summary

Address Information

Account Holder Name: Thomas Schmit
Billing Address: [redacted]
Billing Address 2:
City:
State / Province:
Zip / Postal Code:
Country: USA

Account Information

Card Type: Visa
Card Number: **********1019
Decision Number:
Registration Number: 7173-286
Company Name: Liphatech, Inc.
Company Number: 7173
Action Code: R340

Payment Information

Payment Amount: $3,617.00
Transaction Date and Time: 11/24/2010 12:54 EST

*Personal privacy information *

Thomas Schmit

From: paygovadmin@mail.doc.twai.gov
Sent: Wednesday, November 24, 2010 11:55 AM
To: Thomas Schmit
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Transaction Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 251VGV3B
Agency Tracking ID: 74154802285

Account Holder Name: Thomas Schmit
Transaction Type: Sale
Transaction Amount: $3,617.00
Billing Address: [redacted]
City: [redacted]
State/Province: [redacted]
Zip/Postal Code [redacted]
Country: USA
Card Type: Visa
Card Number: **********1019
Transaction Date: Nov 24, 2010 12:54:45 PM

Decision Number:
Registration Number: 7173-286
Company Name: Liphatech, Inc.
Company Number: 7173
Action Code: R340

*Personal privacy information *

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL, SAFETY
AND POLLUTION PREVENTION

AUG - 8 2012

Thomas Schmit
Liphatech
3600 West Elm Street
Milwaukee, WI 53209

Subject: Amended label as required by the Final Biological Opinion for Rozol Use on Black-tailed Prairie Dogs Registered Under Section 3 of FIFRA
Rozol Prairie Dog Bait
EPA Registration No. 7173-286
Your application dated April 16, 2012

Dear Mr. Schmit:

The label referred to above, submitted under FIFRA, as amended, is **acceptable**. Please submit one final printed copy for the above mentioned label before releasing the product for shipment. If you have any questions, please contact me at (703) 308-6249 or via email at hebert.john@epa.gov.

Sincerely,

John Hebert
Product Manager 07
Insecticide-Rodenticide Branch
Registration Division (7505P)

RESTRICTED USE PESTICIDE
DUE TO HAZARD TO NONTARGET ORGANISMS
For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certificate.

ROZOL®
PRAIRIE DOG BAIT

Active Ingredient: chlorophacinone	0.005%
Inert Ingredients	99.995%
Total	100.000%

EPA Reg. No. 7173-286 EPA Est. No. 7173-WI-1

KEEP OUT OF REACH OF CHILDREN

CAUTION: See side panel for additional precautionary statements.

ACCEPTED
AUG - 8 2012
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide Registered under EPA Reg. No. 7173-286

(Liphatech Logo)
Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209
(414) 351-1476

Net Weight: 1 pound up to 2000 pounds

WARRANTY: To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of product when such use and/or handling is contrary to label instructions.

Side Panel:

PRECAUTIONARY STATEMENTS
Hazard to Humans and Domestic Animals

CAUTION: Harmful if swallowed or absorbed through the skin because it may reduce the clotting ability of blood and cause bleeding. Keep away from children, domestic animals and pets. Do not get in eyes on skin or on clothing. All handlers (including applicators) must wear shoes plus socks, and gloves. Any person who retrieves carcasses or unused bait following application of this product must wear gloves.

USER SAFETY REQUIREMENTS: Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands thoroughly after applying bait and before eating, drinking, chewing gum, using tobacco or using the toilet and change into clean clothing.

FIRST AID: Have label when obtaining treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor.

If on skin: Take off contaminated clothing. Rinse skin with plenty of cool water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

TREATMENT FOR PET POISONING: If animal eats bait, call veterinarian at once.

NOTE TO PHYSICIAN OR VETERINARIAN: Contains chlorophacinone, an anticoagulant. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. For humans or dogs that have ingested this product and/or have obvious poisoning symptoms (bleeding or prolonged prothrombin times), give Vitamin K_1 intramuscularly or orally.

ENVIRONMENTAL HAZARDS: This product is toxic to fish and wildlife. Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten this bait. Do not apply directly to water, or to areas where surface water is present. Do not contaminate water by cleaning of equipment or disposal of wastes. Runoff also may be hazardous to aquatic organisms in water adjacent to treated areas.

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in a cool, dry place inaccessible to children and pets.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of in trash or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. **[Plastic:]** Completely empty container, then offer for recycling or reconditioning; or puncture and dispose of in a sanitary landfill. **[Paper:]** Completely empty container, then dispose of empty container in trash or at an approved waste disposal facility.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL and follow all use directions and precautions. Only use for sites, pests, and application methods specified on this label.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Dispose of product container, unused, spoiled and unconsumed bait as specified on this label.

Use restrictions: This product may only be used as follows:

1. **Sites/Pests:** Black-Tailed Prairie Dogs (*Cynomys ludovicianus*) on rangeland and adjacent noncrop areas.
2. **States:** Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas and Wyoming. Do not apply this product within the exterior boundaries of the Crow Reservation or the Blackfeet Reservation in Montana.

3. **Application Method:** Hand application of bait, at least 6 inches down prairie dog burrows. This product may only be used in underground applications. Do not apply bait on or above ground level. Treat only active burrows.
4. **Treatment Period:** Apply between October 1 and March 15 of the following year, when animals will most readily take the grain bait.
5. **Non-Applicators:** Do not allow children, pets, domestic animals or persons not involved in the application to be in the area where the product is being applied.
6. **Grazing Restriction:** Do not allow livestock to graze in treated areas for 14 days after treatment and when no bait is found above ground.
7. Do not use any other rodenticides containing anticoagulants (diphacinone) in prairie dog towns during the treatment period allowed on this label.

Endangered Species: It is a Federal offense to use any pesticide in a manner that results in the death of an endangered species. Use of this product may pose a hazard to endangered or threatened species. When using this product, you must follow the measures contained in the Endangered Species Protection Bulletin for the county in which you are applying the product. To obtain Bulletins, no more than six months before using this product, consult http://www.epa.gov/espp/ or call 1-800-447-3813. You must use the Bulletin valid for the month in which you will apply the product.

Site Assessment: Before applying this product, identify active prairie dog burrows by visual observation. The openings of active burrows will generally be free of leaves, seeds, other debris or spider webs, and will show freshly turned earth, and have prairie dog feces nearby.

Application: Apply 1/4 cup (53 grams or nearly 2 ounces) of bait at least 6 inches down active prairie dog burrows. Make sure no bait is left on the soil surface at the time of application. Applicator must retrieve and dispose of any bait that is spilled above ground or placed less than 6 inches down the burrow entrance.

Follow-up: Prairie dogs that have eaten this bait will begin to die off 4 to 5 days after they eat a lethal amount. The applicator must return to the site within 4 days after bait application, and at 1 to 2 day intervals, to collect and properly dispose of any bait or dead or dying prairie dogs found on the surface. Carcass searches must be performed using a line-transect method that completely covers the baited area. Transect center lines must be not more than 200 feet (about 60 meters) apart, and should be considerably less if searches are conducted in more densely vegetated sites. Transect lines may be traveled on foot or by vehicle at a rate not to exceed 4 mph. All carcasses found above ground must be collected and disposed of properly. Continue to collect and dispose of dead or dying prairie dogs and search for non-target animals for at least two weeks, but longer if carcasses are still being found at that time. Carcass collection should occur in late afternoon, near sundown, to reduce the potential of nocturnal animals finding carcasses and dying animals. Bury carcasses on site in holes dug at least 18 inches deep or in inactive burrows (no longer being used by prairie dogs or other species) to avoid non-target animal scavenging. Burial includes covering and packing the hole or burrow with soil. If burial is not practical (due to frozen ground, etc.) and other disposal methods are allowed by state and local authorities, collected carcasses may be disposed of by other methods to insure that the carcasses are inaccessible to scavengers.

All dead or dying non-target animals must be reported to the National Pesticide Information Center 1-800-858-7378 as soon as possible. Any apparently injured or sick Federally listed species must also be immediately reported by calling 303-236-7540 (if located in Kansas, Nebraska, the Dakotas, Montana, Colorado or Wyoming) or 505-248-7889 (if located in Texas, New Mexico or Oklahoma). The Black-footed Ferret Coordinator must also be contacted if ferrets are found during Rozol Prairie Dog Bait applications or carcass searches at 970-897-2730 x224. If live black footed ferrets are found outside reintroduction sites, before, during or after Rozol Prairie Dog Bait application, the Black-footed Ferret Coordinator must be contacted immediately and sufficient time must be allowed for the FWS to capture and relocate the black-footed ferret(s) before Rozol Prairie Dog Bait application.

Reapplication: If prairie dog activity persists several weeks or months after the bait was applied, a second application may be made, by treating burrows in the same manner, time period and procedure as the first application. Follow all application, site assessment and follow-up directions and use restrictions as found above.

LIPHATECH

3600 WEST ELM STREET
MILWAUKEE, WI 53209
Tel: 414/351 1476 800/351 1476
Fax: 414/247 8166

Document Processing Desk (AMEND)
EPA Office of Pesticide Programs (7504P)
One Potomac Yard, Room S4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Mr. John Hebert, Insecticide/Rodenticide Branch

April 16, 2012

Re: Application for amended registration of
Rozol Prairie Dog Bait, EPA Reg. No. 7173-286

Dear Mr. Hebert,

The enclosed application package is submitted in order to modify the label of an existing rodenticide product registration. We believe that this action is a fast track, non-PRIA amendment that requires no fee. is attached.

As a result of the April 9, 2012 publication of the US Fish and Wildlife Service final "Biological Opinion" for Rozol Prairie Dog Bait, we submit this amendment to add the states of New Mexico, North Dakota, Montana and South Dakota to the list of states where this product may be used.

The proposed label also contains specific language about carcass searches, as specified on page 9 or the FWS Biological Opinion. We realize that there may be other changes that need to be made to the cautions and/or directions for use in order to implement the FWS Biological Opinion.

The proposed label submitted today makes no changes to the directions for use that require "Hand application of bait ...". Liphatech has previously submitted a PRIA amendment action (Decision number 442642, PRIA start date 12/21/2010) to address this restriction. We do not want the consideration of the hand application restriction to delay this current fast track amendment. **It is important to Liphatech that any consideration of this restriction does not delay the listing of the four states on our label.**

Thank you for your attention to this matter. Please contact me directly if there is any problem or question concerning this submission.

Sincerely,

Thomas Schmit

Thomas Schmit
Manager of Regulatory Affairs

Please read instructions on reverse before co...ing form. Form Approv... OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
7173-286	Kable Davis	☐ None ☒ Restricted
4. Company/Product (Name)	**PM#**	
Rozol Prairie Dog Bait	Insecticide/Rodenticide Branch	

5. Name and Address of Applicant *(Include ZIP Code)*

Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☒ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Fast-track, non-PRIA amendment application, submitted by Thomas Schmit, 414-410-7230, schmit@liphatech.com,
1) to add New Mexico, North Dakota, Montana and South Dakota to the list of states where this product may be applied;
2) to add carcass search requirements as shown on page 9 of the FWS Biological Opinion for Rozol Prairie dog Bait; and,
3) to make other language changes as may be required to implement the FWS Biological Opinion.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☒ Plastic ☐ Glass ☒ Paper ☐ Other (Specify) _____
** Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container	1 pound up to 2000 pounds	☑ On label

6. Menner in Which Label is Affixed to Product: ☒ Lithograph ☒ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas Schmit	Manager of Regulatory Affairs	(414) 410-7230

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingily false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title
Thomas Schmit	Manager of Regulatory Affairs
4. Typed Name	**5. Date**
Thomas Schmit	16 April 2012

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 25, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MR. THOMAS SCHMIT
LIPHATECH, INC.
3600 W. ELM STREET
MILWAUKEE, WI 53209

PRODUCT NAME: ROZOL PRAIRIE DOG BAIT
COMPANY NAME: LIPHATECH, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 7173-286
EPA RECEIPT DATE: 04/18/12

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 7, at (703) 308-6249.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

'AST-TRACK AMENDMENTS – Completeness Screening Checklist

Expert's In-Processing Signature: Schaible Date: 4/26/12 PM #: 7

EPA Reg. Number: 7173-286	EPA Receipt Date: 4/18/12

	Checklist Item	Yes	No	N/A
1	**Application Form** (EPA Form 8570-1) - signed?	✓		
2	**Confidential Statement of Formula** (EPA Form 8570-29) - signed?			✓
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) - signed?			✓
4	**Formulator's Exemption Statement** (EPA Form 8570-27) - signed?			✓
5	**Data Matrix** (EPA Form 8570-35) [Applicable for adding me-too uses] - signed?			✓
	a) Selective Method?			
	b) Cite-All Method?			
	c) Public copy of Matrix provided? See PR Notice 98-5			
6	**Is Label included?** (5 copies)	✓		
	a) Electronic Label submitted?		✓	
	Comments: - Sig/e			

Fee for Service

{915444*~

This package includes the following

- ○ New Registration
- ◉ Amendment

□ Studies? □ Fee Waiver?

□ volpay % Reduction: ____

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 7

Receipt No. S-	915444
EPA File Symbol/Reg. No.	7173-286
Pin-Punch Date:	4/18/2012

☒ This item is NOT subject to FFS action.

Action Code:

Requested: ____

Granted: ____

Amount Due: $ _____

Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: Steve Schmidt Date: 4/19/12

Remarks:

local authorities, collected carcasses may be disposed of by other methods to insure that the carcasses are inaccessible to scavengers.

All dead or dying non-target animals must be reported to the National Pesticide Information Center 1-800-858-7378 as soon as possible. Any apparently injured or sick Federally listed species must also be immediately reported by calling 303-236-7540 (if located in Kansas, Nebraska, the Dakotas, Montana, Colorado or Wyoming) or 505-248-7889 (if located in Texas, New Mexico or Oklahoma). The Black-footed Ferret Coordinator must also be contacted if ferrets are found during Rozol Prairie Dog Bait applications or carcass searches at 970-897-2730 x224. If live black footed ferrets are found outside reintroduction sites, before, during or after Rozol Prairie Dog Bait application, the Black-footed Ferret Coordinator must be contacted immediately and sufficient time must be allowed for the FWS to capture and relocate the black-footed ferret(s) before Rozol Prairie Dog Bait application.

Rearranging the language in the "Follow up" section as recommended above would also make it clear that users are required to revisit the site for at least two weeks to search for and collect carcasses. This should significantly improve understanding of the carcass search requirements.

I thank you for this opportunity to comment on the proposed amended labeling for Rozol Prairie Dog Bait. Please contact me at 701-328-4754 or goehring@nd.gov with any questions or concerns.

Sincerely,

Doug Goehring
Agriculture Commissioner

Proposed Approval of Revised Label for Rozol Prairie Dog Bait (EPA Registration No. 7173-286)

Approved by: Lois Rossi

Lois Rossi, Director
Registration Division

Date: June 21, 2012

Regulatory Rationale

The U.S. Environmental Protection Agency (hereon referred to as EPA or the Agency) is proposing to approve an amended label for the Rozol Prairie Dog Bait (EPA Registration No. 7173-286). Rozol Prairie Dog Bait is a rodenticide containing the anti-coagulant chlorophacinone. It is currently registered for use to control Black-Tailed Prairie Dogs (*Cynomys ludovicianus*) in Colorado, Kansas, Nebraska, Oklahoma, Texas and Wyoming.

Regulatory History

In 2009, EPA issued a registration for the use of Rozol Prairie Dog Bait in 10 states (Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming) pursuant to the provisions of section 3(c) of FIFRA. On September 30, 2010, EPA initiated endangered species consultation with the United States Fish and Wildlife Service ("FWS") regarding the use of Rozol Prairie Dog Bait in those 10 states. Because EPA had not yet completed the consultation, on July 27, 2011, the U.S. District Court for the District of Columbia issued an order requiring EPA to take certain measures to limit the geographic scope of authorized use until it had completed its consultation with FWS. See *Defenders of Wildlife v. Jackson*, No. 09-cv-1814, July 27, 2011. Pursuant to the Court's Order, on August 8, 2011, EPA approved an application from the product registrant (Liphatech, Inc.) to amend the registration for this product. The registration amendment removed Montana, New Mexico, North Dakota, and South Dakota from the list of states where use is authorized.

On January 16, 2012, EPA received a *Draft Biological Opinion For Rozol Use on Black-tailed Prairie Dogs Registered under Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act* ("Draft Biological Opinion") from FWS. EPA provided notice and opportunity for public comment on the Draft Biological Opinion. See Docket number EPA-HQ-OPP-2011-0909-0036. On April 10, 2012, EPA received the *Final Biological Opinion For Rozol Use on Black-tailed Prairie Dogs Registered Under Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act* from FWS ("Final Biological Opinion"), available on-line at http://www.epa.gov/espp and at Docket number EPA-HQ-OPP-2011-0909-0140. The Final Biological Opinion reached the conclusion, predicated on the implementation of certain conservation measures, that use of Rozol Prairie Dog bait is not likely to jeopardize the continued existence of species listed under the Endangered Species Act.

Pending Application

Following completion of endangered species consultation between EPA and FWS, EPA received, on April 18, 2012, an application as described below to amend the registration of Rozol Prairie Dog Bait, pursuant to the provisions of section 3(c) of FIFRA. Liphatech, Inc. proposed to revise the currently accepted label by:

- Modifying use restrictions to allow for use in Montana, New Mexico, North Dakota, and South Dakota;
- Changing carcass search requirements to reflect the terms of the Final Biological Opinion;
- Modifying registration to implement the Final Biological Opinion;

- Including a reference to the EPA's Endangered Species Protection Bulletins, which indicate areas within the ten states where Rozol Prairie Dog Bait use will be restricted;
- Adding a restriction that prohibits the use of more than one anticoagulant rodenticide for control of black tailed prairie dogs per use season. (See Docket number EPA-HQ-OPP-2012-0365)

After considering the existing chlorophacinone database (including the Final Biological Opinion) and the proposed label changes, the Agency is proposing to grant this label amendment for Rozol Prairie Dog Bait, because the label amendment would:

- Implement the conservation measures upon which the Final Biological Opinion was predicated, and
- Implement additional Reasonable and Prudent Measures specified by FWS in the Final Biological Opinion.

The proposed grant of label amendment would also reauthorize use in four states (Montana, New Mexico, North Dakota, and South Dakota), consistent with the scope of the registration prior to the August 8, 2011 EPA grant of label amendment to implement the July 27, 2011 Court Order in *Defenders of Wildlife v. Jackson.* The restoration of use in these four states would be consistent with the terms of the Court Order because FWS has now issued the Final Biological Opinion, relating to the use of Rozol Prairie Dog Bait to control black-tailed prairie dogs.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL, SAFETY
AND POLLUTION PREVENTION

AUG - 8 2012

DECISION MEMORANDUM

SUBJECT: Approval of Revised Label for Rozol Prairie Dog Bait (EPA Reg. No. 7173-286)

FROM: Lois Rossi, Director
Registration Division

TO: Steven Bradbury, PhD., Director
Office of Pesticide Programs

This memorandum recommends that you concur on the approval of the revised label for Rozol Prairie Dog Bait (EPA Reg. No. 7173-286), an end-use product containing the active ingredient chlorophacinone. On April 10, 2012, EPA received the *Final Biological Opinion For Rozol Use on Black-tailed Prairie Dogs Registered Under Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act* from FWS. The Final Biological Opinion reached the conclusion, predicated on the implementation of certain conservation measures, that use of Rozol Prairie Dog bait is not likely to jeopardize the continued existence of species listed under the Endangered Species Act. The proposed label submitted by Liphatech will implement the conservation measures and Reasonable and Prudent Measures specified in the Biological Opinion.

COMMENTS

Five comments were submitted to the docket during the 30 day comment period:

1. Two comments were submitted by private citizens (North Dakota ranchers) that support the label amendment and continued registration of the product.
2. The North Dakota Stockmen's Association commented that "ranchers need effective management tools.....Rozol is one of the most effective tools for controlling prairie dog populations." The only labeling comment the Association had was that they want EPA to consider adding mechanical application to the label as an acceptable method of application.
3. Although the Fish and Wildlife Service completed the final B.O. for this product, they chose to comment on the resulting label. FWS recommended that the carcass search language be modified to prohibit burial in inactive burrows. They also want the label to reference guidance on the line-transect carcass search methodology. RD believes that the carcass search language should not be revised. This issue was not discussed by FWS during the development of the B. O. Regarding the guidance for line-transect searches, FWS, EPA and Liphatech are currently working together to develop the line-transect

methodology. This methodology will be included in the product stewardship plan and applicator training that are required by the B. O.

4. The North Dakota Department of Agriculture (NDDA) commented on the reporting requirements in the "Follow-up" section of the label. The Department questioned the enforceability of the language. However, as this label language was negotiated as a conservation measure between FWS, Liphatech and EPA, RD recommends that it not be changed. NDDA also had comments on rephrasing and reformatting the label for enhanced clarity. RD agrees that these suggestions provide better wording and will revise the label as follows:
    a. Use Restriction 7 is revised to read: "Do not use any other rodenticide containing an anticoagulant (diphacinone) in prairie dog towns during the treatment period allowed on this label.
    b. The "Follow-up" section of the label has been reorganized and reformatted to better separate the carcass, post application language from the reporting requirements.

RECOMMENDATION

I recommend for the approval of the revised label for Rozol Prairie Dog Bait, under FIFRA Section 3(c).

Concur: _____

Steven Bradbury, PhD., Director
Office of Pesticide Programs

Nonconcur: _____

Steven Bradbury, PhD., Director
Office of Pesticide Programs

clearly understand how long persons must refrain from using anticoagulants. It is likely that the intent of this statement is to prohibit use of other anticoagulants from the October 1 to March 15 use window allowed by the Rozol label. Therefore, the language could be rephrased to simply read, "*Do not use any other rodenticides containing anticoagulants (chlorophacinone or diphacinone) in prairie dog towns during the treatment period allowed on this label.*"

2. Language in the "Follow-up" section requires users to report all dead or dying non-target animals to the National Pesticide Information Center (NPIC) as soon as possible. The language also requires all incidents involving dead or dying listed species to be reported to the U.S. Fish and Wildlife Service. This raises a couple of issues. First, it is unclear how state lead agencies will be able to enforce these restrictions. Will states be notified by these entities when a report is made? How will a user be able to document that they made a report and complied with the reporting requirement? Second, I fear that some landowners may be reluctant to report incidents to NPIC because they do not know how that information will be used or to FWS for fear of federal regulatory action. If the goal is to obtain accurate information on incidents involving non-target species, I recommend that the user be required to report incidents to their state or tribal lead pesticide agency. Agriculture producers would be much more apt to report incidents at the tribal or state level than they would report to a federal agency or national hotline.

3. The "Follow-up" section appears to contain directions in two general themes: a) revisiting the site to search for and dispose of carcasses, and b) reporting non-target species incidents to the appropriate authority. To make it easier to read and to better separate these two themes, I recommend rearranging the language and moving all text after, "All carcasses found..." immediately after the sentence that reads, "Transect lines may be traveled on foot or by vehicle at a rate not to exceed 4 mph."

   Using the existing language, the section would be rearranged to read as follows:

   Follow-up: *Prairie dogs that have eaten this bait will begin to die off 4 to 5 days after they eat a lethal amount. The applicator must return to the site within 4 days after bait application, and at 1 to 2 day intervals, to collect and properly dispose of any bait or dead or dying prairie dogs found on the surface. Carcass searches must be performed using a line-transect method that completely covers the baited area. Transect center lines must be not more than 200 feet (about 60 meters) apart, and should be considerably less if searches are conducted in more densely vegetated sites. Transect lines may be traveled on foot or by vehicle at a rate not to exceed 4 mph. All carcasses found above ground must be collected and disposed of properly. Continue to collect and dispose of dead or dying prairie dogs and search for non-target animals for at least two weeks, but longer if carcasses are still being found at that time. Carcass collection should occur in late afternoon, near sundown, to reduce the potential of nocturnal animals finding carcasses and dying animals. Bury carcasses on site in holes dug at least 18 inches deep or in inactive burrows (no longer being used by prairie dogs or other species) to avoid non-target animal scavenging. Burial includes covering and packing the hole or burrow with soil. If burial is not practical (due to frozen ground, etc.) and other disposal methods are allowed by state and*

COMMISSIONER
DOUG GOEHRING

ndda@nd.gov
www.nd.gov/ndda

NORTH DAKOTA
DEPARTMENT OF AGRICULTURE
STATE CAPITOL
600 E. BOULEVARD AVE. – DEPT. 602
BISMARCK, ND 58505-0020

July 20, 2012

John Hebert
OPP Docket
Environmental Protection Agency
Mailcode 28221T
1200 Pennsylvania Ave., NW
Washington, DC 20460

RE: Comments on Proposed Amended Labeling for Rozol Prairie Dog Bait (EPA Reg. No. 7173-286) (Docket ID No. EPA-HQ-OPP-2012-0365)

Dear Mr. Hebert:

I thank you for the opportunity to comment on the proposed amended label for Rozol Prairie Dog Bait (EPA Reg. No. 7173-286). Please consider these comments as the Agency finalizes the label to implement the Reasonable and Prudent Measures specified by the U.S. Fish and Wildlife Service (FWS) in their recent Biological Opinion.

North Dakota is one of ten states within the range of the black-tailed prairie dog. While important to grassland ecosystems, prairie dogs can also adversely impact the land and compete with livestock for forage. Landowners need effective tools to manage prairie dogs, and very few registered pesticides are available. The Department supports efforts to amend the labeling for Rozol Prairie Dog Bait to help ensure that landowners have this product as a registered option to manage prairie dogs.

The North Dakota Department of Agriculture is the state's lead agency for pesticide regulation and enforcement. In that role, the Department conducts investigations of pesticide distributors, dealers, and applicators to ensure compliance with state and federal laws and regulations. Therefore, the Department will be responsible for enforcing the amended labeling if and when it is finalized.

The proposed label reads well, and all restrictions and precautions are generally written in clear, concise, and enforceable language. I would offer the following comments and suggestions as the language is finalized:

1. Item number 7 in the "Reapplication" section reads, "*In each treatment area, only one anticoagulant rodenticide active ingredient (chlorophacinone or diphacinone) may be used per treatment period.*" If this statement is meant to be enforceable, I would urge you to better define "treatment period" so that users and regulators

MEMORANDUM

SUBJECT: Posting EPA-HQ-OPP-2012-0365 to Regulations.gov for Public Access

FROM: Lois Rossi, Director
Registration Division

Lois Rossi 6/21/12

Thru: John Hebert
Insecticide-Rodenticide Branch, Registration Division

This memorandum authorizes the posting of EPA-HQ-OPP-2012-0365 to Regulations.gov for public access.

The U.S. EPA is proposing to approve an amended label for the Rozol Prairie Dog Bait (EPA Registration No. 7173-286). After considering the existing chlorophacinone database (including the *Final Biological Opinion For Rozol Use on Black-tailed Prairie Dogs Registered Under Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act* provided by FWS) and the proposed label changes, the Agency is proposing to grant this label amendment because the amendment would implement the conservation measures upon which the Final Biological Opinion was predicated, and implement additional Reasonable and Prudent Measures specified by FWS in the Final Biological Opinion. The proposed grant of label amendment would also reauthorize use in four states (Montana, New Mexico, North Dakota, and South Dakota).

This document will be open for public comment from 06/21/2012 to 07/20/2012.

Submit your comments, identified by Docket ID No. EPA-HQ-OPP-2012-0365, by one of the following methods:

- www.regulations.gov: Follow the on-line instructions for submitting comments.
- Mail: OPP Docket, Environmental Protection Agency, Mailcode 28221T, 1200 Pennsylvania Ave, NW, Washington, DC 20460.
- Hand Delivery: EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

EPA's policy is that all comments received will be included in the public docket without change and may be made available online at http://www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through http://www.regulations.gov or e-mail. The http://www.regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through

http://www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, avoid any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at http://www.epa.gov/epahome/dockets.htm.

Should you have any questions regarding this memorandum, please contact John Hebert at (703) 308-6249, or via email at hebert.john@epa.gov.

Pages 144-145 - *Internal deliberative information *

Fw: Draft Bulletins for Rozol - 2 of 6 e-mails
Anita Pease to: Melissa Grable, John Hebert 03/22/2012 07:50 AM

We should add this to the list of items to discuss today....just to acknowledge that the grizzly bear timing restriction will be changed from March 15 to March 1.

****

Anita Pease
Associate Director
Environmental Fate and Effects Division
Office of Pesticide Programs, U.S. EPA
1200 Pennsylvania Ave. NW (7507P)
Washington, DC 20460
Phone: 703-305-0392
Fax: 703-305-6309

----- Forwarded by Anita Pease/DC/USEPA/US on 03/22/2012 07:49 AM -----

From:	Scott_Larson@fws.gov
To:	Melissa Grable/DC/USEPA/US@EPA
Cc:	Nancy_Golden@fws.gov, Natalie_Gates@fws.gov, Meredith Laws/DC/USEPA/US@EPA, Anita Pease/DC/USEPA/US@EPA
Date:	03/21/2012 05:59 PM
Subject:	Re: Draft Bulletins for Rozol - 2 of 6 e-mails

Melissa,

This has already been discovered but grizzly timing restrictions in MT should reflect the March 1 date on the county bulletins instead of the March 15 date.

Thank You
Scott Larson
Field Supervisor
U.S. Fish and Wildlife Service
Suite 400
420 South Garfield Ave.
Pierre, South Dakota 57501

Phone: 605-224-8693 x 224
Fax: 605-224-9974
Email: scott_larson@fws.gov

Melissa Grable <Grable.Melissa@epamail.epa.gov>

M
el ToDelfinia_Montano@fws.gov, Don_Morgan@fws.gov,

ss
a
G
ra
bl
e
<
G
ra
bl
e.
M
eli
ss
a
@
ep
a
m
ail
.e
pa
.g
ov
>

03
/0
8/
20
12
06
:3
0
P
M

Nancy_Golden@fws.gov, Sarena_Selbo@fws.gov, gary_frazer@fws.gov, keith_paul@fws.gov, matt_schwarz@fws.gov, paul_souza@fws.gov, scott_larson@fws.gov, bridget_fahey@fws.gov, michael_thabault@fws.gov

ccAnita Pease <Pease.Anita@epamail.epa.gov>, John Hebert <Hebert.John@epamail.epa.gov>

SubjectDraft Bulletins for Rozol - 2 of 6 e-mails

We are providing PDF files of each draft Bulletin for the 6 states and 48 counties in which Rozol Prairie Dog Bait for the control of black-tailed prairie dogs is subject to limitations as a result of the Conservation Measures agreed to by EPA, Liphatech, and U.S. FWS. These agreements were documented in a letter dated December 13, 2011 from EPA to Liphatech and FWS. This letter can be found in the Rozol public docket. Please confirm that you have received this e-mail transmitting the PDF files of the draft Bulletins.

Comments from you and/or other affected parties on the draft Bulletins
must be provided to EPA no later than March 22, 2012.

Comments and input on the draft Bulletins may be sent via e-mail to:

grable.melissa@epa.gov

or you may send comments by FedEx, UPS, or courier to:

Melissa Grable
Environmental Fate and Effects Division (7507P)
Potomac Yards South Room 12713
2777 South Crystal Drive
Arlington, CA 22202

Thank you,
Melissa

(See attached file: Montana.zip)

Melissa Grable
Biologist
U.S. Environmental Protection Agency
OCSPP/OPP/EFED
grable.melissa@epa.gov
(703) 308-3953*(See attached file: Montana.zip)[attachment "pic18678.gif" deleted by Anita Pease/DC/USEPA/US]*

********** ATTACHMENT NOT DELIVERED **********

This Email message contained an attachment named
Montana.zip
which may be a computer program. This attached computer program could contain a computer virus which could cause harm to EPA's computers, network, and data. The attachment has been deleted.

This was done to limit the distribution of computer viruses introduced into the EPA network. EPA is deleting all computer program attachments sent from the Internet into the agency via Email.

If the message sender is known and the attachment was legitimate, you should contact the sender and request that they rename the file name extension and resend the Email with the renamed attachment. After receiving the revised Email, containing the renamed attachment, you can rename the file extension to its correct name.

For further information, please contact the EPA Call Center at (866) 411-4EPA (4372). The TDD number is (866) 489-4900.

********** ATTACHMENT NOT DELIVERED **********

To: Anita Pease/DC/USEPA/US, Melissa Grable/DC/USEPA/US,
Cc:
Bcc:
Subject: Fw: Draft Bulletins for Rozol

Unless you think otherwise, I think we should also add this to the list of discussion topics. Thanks....

John Hebert, PM7
Insecticide-Rodenticide Branch
Registration Division
Office of Pesticide Programs
703-308-6249
----- Forwarded by John Hebert/DC/USEPA/US on 03/22/2012 10:36 AM -----

From: Thomas Schmit <SchmitT@liphatech.com>
To: Melissa Grable/DC/USEPA/US@EPA
Cc: Anita Pease/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA, Al Smith <SmithA@liphatech.com>, Carl Tanner <TannerC@liphatech.com>
Date: 03/22/2012 09:22 AM
Subject: RE: Draft Bulletins for Rozol

Melissa –

We agree with the words written in J. Heberts' letter dated Dec. 13, 2011. For example, Item 12 concerning the Rosebud Indian Reservation: "Rozol use would be prohibited on Tribal lands within the Rosebud Indian Reservation." We agreed to this restriction; we did not agree to any specific map or shape file.

We simply request that the maps accurately reflect the restriction. Currently, the maps show the whole of Todd county of as the Rosebud Indian Reservation. This does not accurately reflect the restriction, and will cause significant confusion among the user community. To accurately reflect the restriction, the map should show only the Tribal lands within the reservation.

We understand that you are using maps provided to you by FWS. Please ask FWS to provide a map that correctly shows the restriction.

Until the map can be corrected, we request that you add a clarifying statement to the bulletins for Todd county and Dewey county to clearly state that Rozol Prairie Dog Bait may be used on private land (ie non-Tribal land) within the county.

Thanks –
Tom

reservation boundary – county bulletin contain explicit statement @ left statement. ?

From: Melissa Grable [mailto:Grable.Melissa@epamail.epa.gov]

Sent: Wednesday, March 21, 2012 11:50 AM
To: Thomas Schmit
Cc: Anita Pease; John Hebert; Al Smith; Carl Tanner
Subject: RE: Draft Bulletins for Rozol

Tom,

These agreements were documented in the letter from EPA to Liphatech and FWS dated December 13, 2011. This letter can be found in the Rozol docket (EPA-HQ-OPP-2011-0909-033). A number of figures showing the agreed to shapefiles were attached to this letter. These shapefiles can be found in the Rozol docket (EPA-HQ-OPP-2011-0909-034). Figure 6 shows the agreed upon shapefile for the Cheyenne River Indian Reservation that covers Dewey and Ziebach counties in South Dakota. Also on this figure is the limitation that Rozol use is prohibited on Tribal lands within the Cheyenne River Indian Reservation. Figure 8 shows the agreed upon shapefile for the Rosebud Indian Reservation which covers Todd County, South Dakota. This figure also shows the limitation that Rozol use is prohibited on Tribal lands within the Rosebud Indian Reservation. These are the shapefiles that were received from FWS and agreed to by all parties as documented in this letter.

Melissa Grable
Biologist
U.S. Environmental Protection Agency
OCSPP/OPP/EFED
grable.melissa@epa.gov
(703) 308-3953

Thomas Schmit ---03/21/2012 09:35:08 AM---Melissa – We disagree with the way an entire county is shown as a "limitation area"

From: Thomas Schmit <SchmitT@liphatech.com>
To: Melissa Grable/DC/USEPA/US@EPA
Cc: Anita Pease/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA, Al Smith <SmithA@liphatech.com>, Carl Tanner <TannerC@liphatech.com>
Date: 03/21/2012 09:35 AM
Subject: RE: Draft Bulletins for Rozol

Melissa –

We disagree with the way an entire county is shown as a "limitation area"
when the limitation concerns only the tribal lands.
It was confusing to us, and will certainly be confusing to the user
community. Why can't the bulletins show the tribal lands as the
"limitation area"?

Tom

From: Melissa Grable [mailto:Grable.Melissa@epamail.epa.gov]
Sent: Wednesday, March 21, 2012 8:31 AM
To: Thomas Schmit

Cc: Anita Pease; John Hebert; Al Smith; Carl Tanner
Subject: RE: Draft Bulletins for Rozol

Tom,

Platte County, Wyoming: Good catch! Thanks! I must have clicked the wrong thing when making the Bulletins. You are correct that it should be the Preble's meadow jumping mouse. This will be fixed before the final Bulletins are issued.

Todd County, South Dakota: The entire county is shown as a limitation area and the limitation in that area is that Rozol use is prohibited on Tribal lands within the Indian Reservation.

Dewey County, South Dakota: Again, the patterned area is a limitation area and the limitation in that area is that Rozol use is prohibited on Tribal lands within the Indian Reservation.

Bulletins, in general, are active ingredient specific as that is how we typically assess risk - by active ingredient. However, since in this case we looked at a specific product, in this case, the Bulletins are product specific. The Bulletins are not species specific.

Thank you,
Melissa

Melissa Grable
Biologist
U.S. Environmental Protection Agency
OCSPP/OPP/EFED
grable.melissa@epa.gov
(703) 308-3953

Thomas Schmit ---03/20/2012 11:37:20 AM---Hello Melissa - Here are our questions after reviewing the draft bulletins:

From: Thomas Schmit <SchmitT@liphatech.com>
To: Melissa Grable/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA
Cc: Anita Pease/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA, Al Smith <SmithA@liphatech.com>, Carl Tanner <TannerC@liphatech.com>
Date: 03/20/2012 11:37 AM
Subject: RE: Draft Bulletins for Rozol

Hello Melissa -

Here are our questions after reviewing the draft bulletins:

Platte County, Wyoming
o There appears to be an error in the species listed - Black Footed Ferret. Should this species be the Preble's Meadow Jumping Mouse based on the Codes and Limitations section of this bulletin?

Todd County, South Dakota
o Why is the entire county shown as an Indian Reservation?
The Jackson County, South Dakota Bulletin seems to show the Rose Bud Indian Reservation
as a small portion of Todd County. We know farmers and ranchers who own

non-reservation
property and live in Todd County, South Dakota.

Dewey County, South Dakota
o Does the Cheyenne Indian Reservation include all of the patterned area shown? If not, the Codes and Limitations section is incorrect.
If this is not all Indian Reservation, yet does contain Black Footed Ferrets, an R1 Rozol use is prohibited in this area, needs to be added.

In addition to the above specific questions, a more general question exists regarding
these county bulletins. Are these bulletins product specific or endangered species specific?
If endangered species specific, why don't they show the restrictions on zinc phosphide
In these same areas of Black Footed Ferrets?

Thanks for the opportunity to comment!
Tom Schmit
Liphatech, Inc.

-----Original Message-----
From: Melissa Grable [mailto:Grable.Melissa@epamail.epa.gov]
Sent: Thursday, March 08, 2012 1:19 PM
To: Thomas Schmit; Carl Tanner
Cc: Anita Pease; John Hebert
Subject: Draft Bulletins for Rozol

Tom and Carl,

We are providing PDF files of each draft Bulletin for the six states and 48 counties in which Rozol Prairie Dog Bait for the control of black-tailed prairie dogs is subject to limitations as a result of the Conservation Measures agreed to by EPA, Liphatech, and U.S. FWS. These agreements were documented in a letter dated December 13, 2011 from EPA to Liphatech and FWS. This letter can be found in the Rozol public docket. Please confirm that you have received this e-mail transmitting the PDF files of the draft Bulletins.

Comments from you and/or other affected parties on the draft Bulletins must be provided to EPA no later than March 22, 2012.

Comments and input on the draft Bulletins may be sent via e-mail to:

grable.melissa@epa.gov

or you may send comments by FedEx, UPS, or courier to:

Melissa Grable
Environmental Fate and Effects Division (7507P) Potomac Yards South Room 12713
2777 South Crystal Drive
Arlington, CA 22202

Thank you,
Melissa

(See attached file: Wyoming.zip)(See attached file: Colorado.zip)(See attached file: Montana.zip)(See attached file: New Mexico.zip)(See attached file: South Dakota.zip)(See attached file: Logan, Kansas
03_06_12.pdf)

Melissa Grable
Biologist
U.S. Environmental Protection Agency
OCSPP/OPP/EFED
grable.melissa@epa.gov
(703) 308-3953

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MAR 9 - 2012

March 9, 2012

Michael Thabault
Assistant Regional Director, Ecological Services
Fish and Wildlife Service (Mountain-Prairie Region)
United States Department of the Interior
Post Office Box 25486
Denver Federal Center
Denver, Colorado 80225-0486

Dear Mr. Thabault,

This letter transmits U.S. Environmental Protection Agency's (EPA) comments on the U.S. Fish and Wildlife Service (FWS) January 16, 2012, Draft Biological Opinion (BiOp) relative to the potential effects from the application of Rozol® Prairie Dog Bait (EPA Reg. No. 7173-286) for Black-tailed Prairie Dog (*Cynomys ludovicianus*) control to the following federally listed threatened or endangered species: American Burying Beetle (*Nicrophorus americanus*), Black-capped Vireo (*Vireo atricapilla*), Black-footed Ferret (*Mustela nigripes*), Canada Lynx (*Lynx Canadensis*), Chiricahua Leopard Frog (*Lithobates [Rana] chiricahuensis*), Eskimo Curlew (*Numenius borealis*), Golden-cheeked Warbler (*Dendroica chrysoparia*), Gray Wolf (*Canis lupus*), Grizzly Bear (*Ursus arctos horribilis*), Gulf Coast Jaguarundi (*Herpailurus (=Felis) yagouaroundi cacomitli*), Jaguar (*Panthera onca*), Mexican Spotted Owl (*Strix occidentalis lucida*), New Mexican Ridge-nosed Rattlensake (*Crotalus willardi obscurus*), Northern Aplomado Falcon (*Falco femoralis septentrionalis*), Ocelot (*Leoardys pardalis*), Piping Plover (*Charadrius melodus*), Preble's Meadow Jumping Mouse (*Zapus hudsonius preblei*), and Whooping Crane (*Crus americana*). Throughout these comments, Rozol will be used to refer to the specific product Rozol® Prairie Dog Bait (EPA Reg. No. 7173-286). EPA appreciates the communication with FWS regarding this draft BiOp and anticipates continued communication as the BiOp is finalized. EPAs comments on the draft BiOp are included in the Attachment and are organized in the following sections:

- EPA Comments on Conservation Measures
- EPA Comments on Draft Reasonable and Prudent Measures
- EPA Comments on Scope of the Draft BiOp
- EPA Comments on Label Directions and Off-label Uses
- EPA Comments on Potential Exposure for Secondary Toxicity
- EPA Comments on Toxicity, Risk Estimation, and Risk Characterization
- EPA Comments on Incidents, and
- Other EPA Comments.

EPA makes draft BiOps available through the EPA web site (http://www.epa.gov/oppfead1/endanger/) and the public docket for purposes of obtaining comments on draft Reasonable and Prudent Measures and Alternatives. EPA has made clear on its web site and in the docket that any comments on other aspects of the draft BiOp submitted to EPA will be provided to FWS for consideration during development of the final BiOp. I appreciate your consideration of the comments EPA has received in the public docket related to this Draft BiOp (Docket No. EPA-HQ-OPP-2011-0909). This would include all comments with a posting date since January 17, 2012 (the date on which EPA posted the Draft BiOp to the Docket). For your convenience in retrieving these public comments, the docket may be accessed at: http://www.regulations.gov/#!docketDetail;dct=FR%252BPR%252BN%252BO%252BSR%252BPS;rpp=25;po=0;D=EPA-HQ-OPP-2011-0909. An attachment (Excel spreadsheet, created using the 'export' function on the docket webpage) is provided that contains hyperlinks to each of the individual comments as well as to all the supporting material that was posted to the docket.

We look forward to continued collaboration with FWS in achieving a successful formal Section 7 consultation which will result in a final BiOp in 30 days that contains reasonable protections for listed species that co-occur in the area of Rozol use to control black-tailed prairie dogs. Please do not hesitate to contact me at (703)-305-7090 if you have any questions.

Sincerely,

Steven Bradbury, Ph.D., Director
Office of Pesticide Programs

Attachments

cc: David Berol
Donald Brady
Mark Dyner
Catherine Eiden
John Hebert
Richard Keigwin
Meredith Laws
Anita Pease
Lois Rossi

Attachment 1: EPA Comments on the FWS Draft BiOp for Rozol (dated January 16, 2012)

EPA Comments on the Conservation Measures

Black-footed Ferret Conservation Measure. EPA received from FWS the Geographic Information System (GIS) shapefiles for the current 13 black-footed ferret reintroduction areas. EPA requests that the delivery of GIS shapefiles for future black-footed ferret release sites be provided to the EPA in a timely manner. Timely delivery of these shapefiles is important as EPA requires approximately eight months before new maps in the Endangered Species Protection Bulletins (hereafter referred to as Bulletins) can be officially implemented via the EPA County Bulletin website (*Bulletins Live!)*. Once the Bulletins are implemented in *Bulletins Live!,* they become an enforceable part of the pesticide label. Eight months from receipt of the shapefiles to implementation in *Bulletins Live!* provides for approximately two months for public comment and revisions, as well as six months for the regulated community to plan for upcoming pesticide applications. These timelines are described in the Bulletins implementation documentation (http://www.epa.gov/fedrgstr/EPA-PEST/2005/November/Day-02/p21838.htm).

Grizzly Bear Conservation Measure: The draft BiOp states that the application period for Rozol shall be restricted to December 1 to March 1 in areas where the range of the grizzly bear overlaps with the range of the black-tailed prairie dog. Previous agreements made between FWS, Liphatech, and EPA resulted in a Conservation Measure for the grizzly bear with an application period for Rozol from December 1 to March 15 in areas where the range of the grizzly bear overlaps with the range of the black-tailed prairie dog (December 13, 2011 letter from EPA to FWS and Liphatech, Docket IDs EPA-HQ-OPP-2011-0909-0033). If this is a typographical error, EPA requests that in the final BiOp this Conservation Measure be written to reflect the previously agreed upon application window (December 1 to March 15) within the grizzly bear range. If FWS has become aware of new information that supports a shorter application window (December 1 to March 1), FWS is requested to share that information with EPA.

Preble's Meadow Jumping Mouse Conservation Measure: EPA noted an inconsistency between the GIS shapefiles provided by FWS and the geographic areas for timing prohibitions specified in the draft BiOp. Conservation measures related to Rozol timing prohibitions for the Preble's meadow jumping mouse in the draft BiOp (page 8) include the following seven counties in Colorado: Boulder, Douglas, El Paso, Elbert, Jefferson, Larimer, and Weld. The species description in the draft BiOp (page 40) indicates that the known distribution of the Preble's meadow jumping mouse in Colorado includes Boulder, Douglas, El Paso, Elbert, Jefferson, Larimer, Teller, and Weld counties. EPA assumes that FWS intended to list Teller County, Colorado in the Conservation Measure for Preble's meadow jumping mouse on page 8 of the draft BiOp, and is including pesticide use limitations within Teller County as part of the County Bulletins for the Preble's Meadow Jumping Mouse.

The GIS shapefiles provided by FWS also included areas in Goshen County, Wyoming, and areas in the following Colorado counties: Adams, Arapahoe, Clear Creek,

Gilpin, Grand, Jackson, Lincoln, and Park. These counties are not specifically named in the draft BiOp as counties where the Preble's meadow jumping mouse is found; therefore, EPA plans to exclude these counties from the Bulletins. Please provide comments if EPA's conclusion regarding the counties that should be included in the maps is incorrect.

EPA Comments on Draft Reasonable and Prudent Measures

EPA's comments on RPMs are reflective of oral agreements, as appropriate, based on a February 2, 2012 meeting between EPA, FWS, and Liphatech. Comments on the RPMs are subdivided into the following categories:

- Establishment and modification of Bulletins,
- Draft reporting requirements,
- Draft RPMs to be reclassified as Conservation Recommendations, and
- Draft outreach-related activities.

Establishment and modification of Bulletins

- **Black-footed ferret (BFF) RPM 1:** *EPA will ensure Rozol will not be used in current and future ferret reintroduction areas.*
  In the event that Bulletins are necessary to cover the geographic range of future ferret reintroduction areas, EPA intends to modify the Bulletins as appropriate. EPA requests that the delivery of GIS shapefiles for future black-footed ferret release sites be provided to the EPA in a timely manner. Timely delivery of these shapefiles is important as EPA requires approximately eight months before the these new maps in the Bulletins can be officially implemented via *Bulletins Live!*. Once the Bulletins are implemented in *Bulletins Live!,* they become an enforceable part of the pesticide label. The approximate eight months from receipt of the shapefiles to implementation in *Bulletins Live!* provides two months for public comment and revisions, as well as six months for the regulated community to plan for upcoming pesticide applications. The RPM's terms and conditions should be modified to expressly accommodate this implementation time, starting from when EPA receives an updated shapefile.

- **BFF RPM 5.** *The EPA will ensure that if a previously unknown wild ferret population is discovered, Rozol will not be used on that population.*
  EPA intends to modify the Bulletins to reflect identification of wild ferret populations, should they be discovered. EPA requests that the delivery of GIS shapefiles for wild ferret population sites be provided to the EPA in a timely manner. Timely delivery of these shapefiles is important as EPA requires at least eight months before the these new maps in the Bulletins can be officially implemented via *Bulletins Live!*. Once the Bulletins are implemented in *Bulletins Live!,* they become an enforceable part of the pesticide label. The minimum of eight months from receipt of the shapefiles to implementation in *Bulletins Live!* provides two months for public comment and revisions, as well as six months for the regulated community to plan for upcoming pesticide applications. The RPM's

terms and conditions should be modified to expressly accommodate this implementation time, starting from when EPA receives an updated shapefile.

- **Northern Aplomado Falcon (NAF) RPM 3.** *Within the range of the northern aplomado falcon, maintain the EPA County Bulletin website so that a current listing of counties with habitat for northern aplomado falcons is available to the public.*
  EPA intends to modify the Bulletins to include identification of counties containing habitat for the NAF. EPA requests that the delivery of the county GIS shapefile be provided to the EPA in a timely manner. Timely delivery of these shapefiles is important as EPA requires approximately eight months before the these new maps in the Bulletins can be officially implemented via *Bulletins Live!*. Once the Bulletins are implemented in *Bulletins Live!*, they become an enforceable part of the pesticide label. Approximately eight months from receipt of the shapefiles to implementation in *Bulletins Live!* provides two months for public comment and revisions, as well as six months for the regulated community to plan for upcoming pesticide applications. The RPM's terms and conditions should be modified to expressly accommodate this implementation time, starting from when EPA receives an updated shapefile. As the start of the 2012 Rozol use season is less than eight months away, it is not possible for this RPM to be implemented at the beginning of the 2012 Rozol use season.

Draft reporting requirements

- **BFF RPM 2.** *If an applicator or the EPA becomes aware that a ferret is known to occupy a black-tailed prairie dog colony outside of a reintroduction area, Rozol cannot be used on that colony until the ferret or ferrets have been relocated. The reintroduction site manager should be contacted.*
  EPA intends to modify the labels to state that knowledge of ferrets occupying areas outside of a reintroduction area must be reported to the National Black-Footed Ferret Coordinator (contact information to be provided on label). As orally agreed to by FWS, the National Black-Footed Ferret Coordinator will be responsible for communicating any spatial and/or temporal prohibitions of Rozol use to applicators and stakeholders within the affected area (likely a period of three weeks). In addition, FWS has orally agreed to trap and relocate ferrets found outside of the reintroduction areas. The RPM's terms and conditions should be modified to reflect that this is an appropriate implementation.

- **BFF RPM 3:** *The EPA or an applicator must notify the Service if ferrets or carcasses thereof are found during any Rozol use related activities.*
- **NAF RPM 1:** *Notify the Service if northern aplomado falcons or carcasses thereof are found during any Rozol use activities.*
  The EPA intends to modify existing labels to ensure that any incidents involving the BFF and NAF are collected and reported to the EPA. EPA will then provide Rozol incident reports to FWS. EPA also intends to modify Rozol labels to direct applicators to contact FWS if live BFF or NAF are observed during Rozol use activities. The RPM's terms and conditions should be modified to reflect that this is an appropriate implementation.

- **GW (Grey wolf) RPM 1:** *The EPA shall report, or require applicators to report, all sickened, dying, or dead gray wolves (regardless of their status under the ESA) poisoned as a result of Rozol use on black-tailed prairie dog colonies.*
  The EPA intends to modify existing labels to ensure that incidents involving the GW are collected and reported to the EPA. EPA will then provide Rozol incident reports to FWS. The RPM's terms and conditions should be modified to reflect that this is an appropriate implementation.

- **BFF RPM 4:** *The EPA in cooperation with Liphatech shall develop and maintain a system to track Rozol used for black-tailed prairie dog control and report to the Service the amounts sold/used in each of the ten states.*
- **NAF RPM 2.** *Maintain a system to track Rozol used for black-tailed prairie dog control and report to the Service the amounts sold/used in each of the ten states.*
  In the final BiOp, BFF RPM 4 and NAF RPM 2 should be modified to state that EPA will provide FWS staff with FIFRA Confidential Business Information (CBI) clearance the total annual Rozol production information. The final BiOp should state that this is a time limited requirement and that data will only be provided for three years. The RPM's terms and conditions should be modified to reflect that this is an appropriate implementation.

Draft RPMs to be Reclassified as Conservation Recommendations

- **BFF RPM 6.** *The EPA shall initiate or require studies to evaluate secondary toxicity of the EPA registered prairie dog rodenticides to ferrets.*
- **BFF RPM 7.** *The EPA shall initiate or require studies to demonstrate whether the label requirements that are intended to prevent secondary poisoning of non-target animals is preventing routes of secondary exposure.*
- **GW RPM 2.** *The EPA shall develop means to reduce the amount of Rozol-poisoned black-tailed prairie dogs and non-target species available for gray wolf consumption.*
- **NAF RPM 5.** *Contribute to efforts to re-establish the northern aplomado falcon within its range in the U.S.*
  On February 2, 2012, EPA, FWS, and Liphatech orally agreed three draft RPMs (BFF RPM 6, BFF RPM 7, and NAF RPM 5) should be considered Conservation Recommendations rather than Reasonable and Prudent Measures. EPA believes this agreement is appropriate and that the final BiOp should be revised accordingly.

  In addition, EPA requests that when moving the draft BFF RPM 6 to a Conservation Recommendation, the scope be changed to reflect evaluation of secondary toxicity of Rozol, rather than evaluation of secondary toxicity of "registered prairie dog rodenticides" as the BiOp should only address the proposed action.

  EPA also requests that draft GW RPM 2 be considered a Conservation Recommendation.

  The Service consultation regulations and the draft BiOp defines RPMs to "*include actions that occur within the action area, involve only minor changes to*

the project.....should minimize the impacts of incidental take.....are consistent with the proposed action's basic design, location, scope, duration and timing" (page 59 of the draft BiOp). EPA's concerns regarding these four proposed RPMs is that these RPMs do not involve *minor* changes and that these RPMs would not directly function to minimize impacts of incidental take. For the proposed BFF RPMs, it is unclear how requirements aimed at improving understanding of toxicity and estimating likelihood (or reduction in the likelihood) of secondary exposure occurrences would directly impact the minimization of incidental take. In addition, the BFF RPMs 6 and 7 and GW RPM 2 are similar to the draft Conservation Recommendations for the NAF (page 99-100). Finally, for NAF RPM 5, the proposed requirements address recovery and re-introduction of the NAF, rather than minimization of incidental take.

Draft outreach-related activities

- **NAF RPM 4.** *Within the range of the northern aplomado falcon, inform public users about the risks of Rozol to non-target organisms and how risks can be minimized.*

  Regarding outreach-related activities, it was orally agreed on February 2, 2012, that FWS would allow EPA flexibility in implementing this RPM. For example, EPA could include content provided by FWS on its Endangered Species website (http://www.epa.gov/espp/) as a substitute for the brochure discussed in the implementation steps for NAF RPM 4. Any Web content provided by FWS would need to be reviewed following EPA's standard processes. In addition, this information could also be electronically provided to states that include NAF range to for their use and dissemination during certified applicator training. The RPM's terms and conditions should be modified to reflect that this is an appropriate implementation.

EPA Comments on Scope of the Draft BiOp

Page 11, 2nd paragraph. *Chlorophacinone and diphacinone are the only indandione active ingredient rodenticides currently registered for use in the United States. Both have been registered for use to control black-tailed prairie dogs under FIFRA section 24(c) for Special Local Needs and Rozol has been registered under FIFRA section 3.*
EPA Comment: There are no current registrations in the United States for diphacinone use on black-tailed prairie dogs.

Page 30, 3rd paragraph: *If EPA chooses to continue registration of Rozol and other anticoagulants for use on prairie dogs, it should first develop alternative testing protocols to evaluate their toxicity to non-target species.*
EPA comment: This draft BiOp should address concerns only regarding Rozol use, the federal action which is the subject of this consultation. Inclusion in the BiOp Conservation Measures or Reasonable and Prudent Measures for other chemicals falls outside the scope of the consultation and therefore is not appropriate.

EPA Comments on Label Directions and Off-label Uses

Page 2, third point in time line: *1990's Rozol Pocket Gopher Bait made with chlorophacinone is used off-label on prairie dogs with the EPA's authorization and begins to generate interest as a prairie dog rodenticide (Lee et al. 2005).*
Page 63, 1st paragraph: *... used under Special Local Needs labels for black-tailed prairie dog control since 2004 and as early as 1991 under a pocket gopher formulation (Lee et al. 2005).*
EPA Comment: Chlorophacinone was first approved for use on prairie dogs as a Section 24c registration (Special Local Needs) in Kansas on April 1, 2004. This label (KS-040004) was valid from April 1, 2004, to April 1, 2009. EPA does not have any record of authorization to use Rozol Pocket Gopher Bait in black-tailed prairie dog burrows. Therefore, the use described in Lee *et al.* (2005) was inconsistent with the labeling of EPA-approved products and constituted an illegal use of the pesticide.

Page 14, 1st paragraph: *Bait spilled by applicators or not entirely placed in burrows can be difficult and time consuming to collect.*
Page 16, 5th paragraph: *Even though the current label requires collection and disposal of live prairie dogs, we have encountered applicators who indicate that this is not readily accomplished.*
Page 18, 2nd paragraph: *Pamphlets produced by Liphatech indicate that little effort is needed to meet the Rozol label requirement for carcass searches and disposal of prairie dogs carcasses (Bruesch 2009, Liphatech 2009).*
Page 29, 3rd bullet: *Label requirements aimed at reducing non-target species exposure based on return site visits for weeks after the application to pick up dead and dying prairie dogs and bait are impractical, and not effective at protecting non-target species that may dig up carcasses or feed on poisoned prey during periods between required carcass searches.*
EPA comment: The Rozol label requires the applicator to collect and dispose of any bait found on the ground surface when returning to the site to collect and dispose of dead and dying prairie dogs. The label requires that the applicator must return to the site within 4 days after application and every 1 to 2 days for at least two weeks and longer if carcasses are still being found. It is illegal and a misuse of the product to use it in a manner that is inconsistent with its labeling. Ecological risk assessments conducted by EPA's Environmental Fate and Effects Division (EFED) are conducted based on label language as the legally allowable methods for use. Marketing pamphlets do not absolve the user from the legal requirement to use Rozol consistent with its labeling.

FWS has not demonstrated in the draft BiOp that the return site visits, as required by the label, are 'impractical.' Carcass search and collection as defined by the label will reduce the risk to non-target carnivores and scavengers. The label requires that carcasses be buried at least 18" deep or disposed of using other approved measures (if digging a hole is not possible). EPA is not aware of any instances of non-target animals digging up a properly buried carcass for consumption.

Page 17, 1st paragraph: *Although the Rozol label requires the search and removal of dead and dying prairie dogs following application, the limited information on applicator*

behavior indicates that few if any moribund or dead prairie dogs found on the surface are collected and disposed of in a manner that substantially reduces secondary exposure (Service 2010a, Tosh et al. 2011).

Page 18, 1st paragraph: *A recent on-farm survey on anticoagulant use in Northern Ireland found that applicators seldom followed best practice guidelines designed to maximize efficacy and reduce risk of non-target species exposure. They found that applicators almost never searched for and removed poisoned carcasses and many baited for prolonged periods or permanently.*

EPA comment: It is illegal and a misuse of the product to use it in a manner that is inconsistent with its labeling. Tosh *et al.* (2011) does not discuss prairie dog control, but rather summarizes a survey of farmers in Northern Ireland and their rodenticide use practices. It is unlikely that the survey from Northern Ireland, which mentions baiting as part of the application method, is representative of the Rozol use pattern assessed in this BiOp. It is also unclear whether the label for these anticoagulant use patterns specifies search and removal of carcasses, similar to the U.S. label for Rozol.

Page 17, 1st paragraph: *During a prairie dog meeting in 2010 attended by the EPA and hosted by the North Dakota Department of Agriculture and Standing Rock Sioux Indian Reservation, ranchers and professional pesticide applicators indicated that they do not have the time, resources or inclination to conduct multiple return visits to a Rozol treated prairie dog colony to collect dead and dying prairie dogs, and that current label requirements for two return visits to treated prairie dog towns were unrealistic and impractical.... Of particular note from that meeting was that none of the attendees had ever picked up and disposed of live prairie dogs or their carcasses after Rozol application. The Montana Department of Agriculture also questioned the practicality of the Rozol label, especially the retrieval of live prairie dogs, and expressed their belief that most applicators will have difficulty with strict adherence to the label (de Young 2009).*

EPA Comment: This town-hall type meeting was attended by members of the EPA, FWS, tribal members, ranchers from North and South Dakota, as well as staff from the North and South Dakota Departments of Agriculture. At the time of this meeting, Rozol was not registered for use in South Dakota and it had only been registered for one year in North Dakota. The draft BiOp should include information concerning the timing of the meeting in relationship to the approval of Rozol use in order to provide appropriate context for the statement that "...none of the attendees had ever picked up and disposed of live prairie dogs or their carcasses after Rozol application." EPA thinks it is likely that few, if any, attendees had applied Rozol in prairie dog towns.

EPA Comments on Potential Exposure for Secondary Toxicity

Page 23, paragraph 2: *The highest liver known chlorophacinone concentration in a black-tailed prairie dog is 8.4 µg/g ww in a black-tailed prairie dog that consumed 52.8 grams of Rozol and was euthanized two days later (Witmer 2011).*

EPA comment: EPA encourages submission of Witmer (2011) for review and inclusion in future risk assessments.

Page 27, 3rd paragraph: *Raptors are believed to be especially susceptible to secondary poisoning from Rozol given the likelihood that they can spot dead or dying black-tailed prairie dogs that are more difficult to see from a ground level perspective (Vyas 2010b) and raptors have been observed to be attracted to Rozol poisoned black-tailed prairie dog colonies (Vyas 2010a).*
EPA comment: Vyas (2010a) does not provide any quantitative data or analysis to support the conclusion that raptors are attracted to Rozol poisoned black-tailed prairie dog colonies. Observation of raptors in treated colonies is not sufficient to conclude that raptors preferentially hunt and feed in treated colonies when compared to untreated colonies.

EPA Comments on Toxicity, Risk Estimation, and Risk Characterization

Page 12, 1st paragraph: *For example, the median Lethal Dose (LD50) from a single exposure of chlorophacinone to Norway rats (Rattus norvegicus) is 20.5 micrograms per gram (µg/g), whereas a 5-day daily dose LD50 is 20 times lower at 0.95 µg/g (Jackson and Ashton 1992).*
Page 28, 2nd bullet point: *Chlorophacinone is most toxic when animals are exposed to multiple doses for multiple days. Thus, current required acute standardized toxicity tests for chlorophacinone greatly underestimate risk to non-targets [sic] animals.*
EPA Comment: EPA has reviewed additional data evaluating toxicity of a single acute oral exposure of chlorophacinone to Norway rats (MRID 41875301) that resulted in an LD_{50} of 6.26 µg/g-bw. This endpoint, when compared to the endpoint of 20.5 µg/g-bw reported in the open literature, suggests that Norway rats exhibit a wide range of sensitivity to chlorophacinone. If the LD_{50} of 6.26 µg/g-bw was compared to the total dose administered over five days (Jackson and Ashton 1992), the 5-day daily dose LD50 is 6 times lower. While this is not an insignificant difference, it is much more typical of among-test variability in endpoints when testing methodology (*e.g.*, dose administration) is the same among those tests. Jackson and Ashton (1992) do not present details of the laboratory methods and results (*e.g.*, time to mortality, body weights, raw data, feed consumption, sublethal effects, laboratory conditions) which would add to the characterization of the apparent differences in sensitivities. EPA suggests that presenting this single ratio of LD_{50}s without presenting all available data and uncertainties mischaracterizes the level of confidence in the LD_{50} values.

Toxicity tests using multiple gavage exposures are available for only one species (Norway rat); therefore, the data are insufficient to extrapolate the conclusions to all animals. Use of the dietary LC_{50} toxicity studies (available for both birds and mammals for chlorophacinone) provides an alternative approach to evaluating toxicity with multiple day exposure periods.

Page 14, 2nd paragraph: *The Rozol application rate of approximately ¼ cup of bait (53 grams) down each active prairie dog burrow may be excessive and likely results in increased risk to non-target species... While that level of dosing likely ensures high levels of death to prairie dogs, it likely also contributes to prairie dogs consuming multiple lethal doses as well*

as providing left-over bait to remain available for non-target species to consume after the prairie dogs have been killed.

Page 29, 2nd bullet: *Based on the label application rate, excessive lethal doses per black-tailed prairie dog are likely applied and result in increased risk to non-target species. In addition to having excess bait available for direct consumption by non-target species, over-application and Rozol's prolonged toxic mode of action result in a high risk of secondary exposure to non-target species, especially those species attracted to poisoned black-tailed prairie dog colonies. A six month application season for Rozol can result in a long duration and increased opportunity for repeated exposure to chlorophacinone and/or diphacinone rodenticides as the species migrates or moves within their territory.*

EPA comment: FWS has presented no empirical evidence to demonstrate that "excessive lethal doses" are applied when the label directions are followed. Even if it was concluded that the point estimate ratio of 20 (single dose LD_{50} compared to a 5-day daily dose LD_{50}, page 12 of the draft BiOp) presented by FWS was appropriate to extrapolate to the prairie dog LD_{50}, the statement on page 14 of the draft BiOp "53 grams of bait likely provides at least 10 lethal doses," would only be true if the exposed individuals were the most sensitive and if these individuals consumed a sufficient quantity of bait for five consecutive days. The example in this paragraph does not adequately characterize all the exposure and toxicity uncertainties and presents an unduly conservative scenario.

Although the application season is as long as six months depending on the geographic location, the label restricts re-application to the same location to only twice per season. This restriction and label requirements regarding bait clean-up should eliminate the concern for a 'long duration' exposure expressed by FWS.

Page 12, 1st paragraph: *Likewise, a dietary toxicity test that provided a measured diphacinone-treated diet for daily consumption by eastern screech-owls (*Megascops asio*) found that repeated low-dosage exposure over seven days increased diphacinone toxicity by more than an order of magnitude compared to an acute oral toxicity test (Rattner et al. 2011a; Vyas, personal communication, 2011a).*

EPA Comment: The mode of action of chlorophacinone and diphacinone is similar as these two chemicals belong to the same class; however, the comparison stated above requires additional characterization. This statement compares a "multiple day dietary exposure study" to a "single gavage exposure study" for two different bird species. These differences should be discussed in the BiOp prior to making conclusions regarding toxicity differences.

Page 12, 2nd paragraph: *Mortality from LD50 tests indicate two peaks in the number of black-tailed prairie dog deaths, a larger peak that occurs 9 to14 days after exposure and a second smaller peak that occurs 17 to 20 days after exposure (Yoder 2008).*

EPA Comment: EPA recently finalized its review of the Yoder (2008) study (MRID 47333601). While the reviewer concurred that there was high variability in time to death (9 to 20 days after dosing), the data presented were not adequate (only 10 individuals at each of five dose levels, no strong dose-response relationship, and distance of two days between the "two peaks" very narrow relative to the width of the time to mortality ranges) to characterize the mortality pattern as having two separate peaks.

Page 21, 1st paragaraph: *Given the similarity of chlorophacinone to diphacinone, we conclude that at least raptors (e.g., the northern aplomado falcon), and possibly other groups of species, will exhibit greater sensitivity than can be estimated from existing mallard or northern bobwhite studies.*
EPA comment: While chlorophacinone and diphacinone are similar based on chemical structure and mode of action, similar patterns in differential toxicity to different bird classes (upland game birds compared to raptors) has not been established. Bobwhite quail are not equally sensitive to chlorophacinone (LD_{50} = 258 mg a.i./kg-bw, MRID 41513101) and diphacinone (LD_{50} = 1630 mg a.i./kg-bw, MRID 42245201); therefore, it cannot be presumed that the relative sensitivity of bobwhite quail and American kestrels to diphacinone can be applied to the bobwhite quail data for chlorophacinone. EPA recognizes the possibility that raptors may be more sensitive to both indandione rodenticides, but does not have sufficient information to quantify the increased sensitivity.

Page 21, 2nd paragraph: *Furthermore, the LC50-based TRV does not account for potential sub-lethal effects of chlorophacinone that can decrease listed species survival and/or reproduction. Accounting for sub-lethal effects from chlorophacinone exposure such as fatigue, clotting abnormalities, and hemorrhaging is important when evaluating risk to federally listed species.*
EPA Comment: EPA has issued a Data Call-In (DCI) for avian reproduction studies conducted with chlorophacinone and is anticipating their submission. EPA requests FWS provide a threshold of adverse effects for fatigued animals is using the provided parameters. EPA also requests that FWS provide further information on how it is determined whether "fatigue" is chemically-related or caused by other stressors.

EPA Comments on Incidents

Page 13, 3rd paragraph: *Twenty-nine adult domestic pigeons (*Columba livia*) were poisoned with a 0.005 percent chlorophacinone wheat grain bait after a broadcast application targeted at common voles (*Microtus arvalis*) (Sarabia et al. 2008).*
EPA Comment: This incident occurred in Spain; the product label with application rates and methods is not available for EPA review and for comparison with application methods on labels registered by the EPA. The article does confirm that non-target mortality may occur after ingestion of chlorophacinone bait; however, it is unclear if the exposure scenario and application rate is comparable to Rozol application methods.

Page 13, 3rd paragraph: *Green droppings from these birds suggest they were consuming bait; an assumption subsequently confirmed by detection of chlorophacinone residues in these droppings (Vyas, personal communication, 2011b).*
EPA comment: EPA encourages submission of these data to EPA for review and for possible use in future risk assessments.

Page 19, 4th paragraph: *A Rozol application in South Dakota on a prairie dog colony in 2005 found approximately 400 to 500 dead and dying prairie dogs on the surface when a 160-acre densely populated prairie dog town was treated with Rozol. At that time, Rozol*

was not authorized for use in South Dakota and a subsequent investigation by EPA ensued but the outcome is not available at this time.
Comment: This is an example of an illegal use as Rozol was not authorized for use in South Dakota in 2005.

Page 27, 2nd paragraph: *More dead raptors were found in that same area of Kansas after Rozol was used to control prairie dogs in 2009 including two more ferruginous hawks and a bald eagle that were found shot and thus not tested for chlorophacinone (Service 2009c). Also in that same area of Kansas, Audubon of Kansas reported that in addition to the raptors provided to Service law enforcement in 2009 they had found an additional 17 dead hawks, mostly ferruginous hawks that were not picked up in the field.*
EPA comment: It is unclear whether these wildlife mortalities are attributed to chlorophacinone or Rozol as no definitive testing for chlorophacinone in body tissues was conducted. This level of uncertainty in characterizing the cause of mortality should be clearly stated in the final BiOp.

Other EPA Comments

Page 9, 4th paragraph and Page 10 (figure): *Range maps from NatureServe for federally listed species and/or their critical habitats were overlaid on that historic black-tailed prairie dog map to determine any overlap which was used in the EPA's BA to inform "May Affect" determinations for federally threatened or endangered species and their critical habitats.*
EPA Comment: The map of the historic black-tailed prairie dog range was obtained from NatureServe. The range maps for the listed species found in EPA's BA did not come from NatureServe but rather from the county-level data available for each species on the U.S. Fish and Wildlife's website (http://www.fws.gov/endangered/).

Page 14, 3rd paragraph: *Results from other studies indicate that application rates of less than 53 grams of product per active burrow can be effective at killing black-tailed prairie dogs. Sullins (1990) reported a 96 percent reduction in the visible count of black-tailed prairie dogs after providing 0.01 percent chlorophacinone product in two applications of 9 grams per active burrow for a total of 18 grams within 48 hours.*
EPA comment: The product used in Sullins (1990) has a higher percent active ingredient than Rozol (0.005% a.i.). Assuming 18 grams per burrow of the product used in Sullins (1990), the equivalent amount of Rozol is 36 grams (on a mg chlorophacinone basis) rather than 18 grams as indicated in the draft BiOp. This comparison should be corrected in the BiOp by stating that the 96 percent reduction in visible counts of black-tailed prairie dogs occurred after providing the equivalent of 36 grams of Rozol per active burrow. This is in comparison to the 53 grams of Rozol to be applied in each active burrow based on the label directions.

Page 40, 1st paragraph: *The EPA BA (Appendix A, p.20) erroneously shows the Preble's meadow jumping mouse's range to be throughout all of Wyoming.*

EPA Comment: EPA appreciates the error correction and will ensure that future assessments evaluating the Preble's meadow jumping mouse will use the current range maps.

Pages 168-200 - *Internal deliberative information *

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

PC Code: 067707
DP Barcode: D350010
Date: February 3, 2012
DECISION: 389136

MEMORANDUM

SUBJECT: Environmental Fate and Effects Division Review of an Acute Toxicity Study

TO: Dan Peacock, Risk Manager Reviewer
John Hebert, Risk Manager
Registration Division (7505P)
Office of Pesticide Programs

FROM: Christine Hartless, Wildlife Biologist 2-3-12
Environmental Risk Branch II
Environmental Fate and Effects Division (7507P)
Office of Pesticide Programs

APPROVED BY: for Brian Anderson, Branch Chief 2-3-12
Environmental Risk Branch II
Environmental Fate and Effects Division (7507P)
Office of Pesticide Programs

The Environmental Fate and Effects Division (EFED) has reviewed the following study:

MRID 473336-01
Yoder, C.A. 2008. Acute Oral Toxicity (LD50) of Chlorophacinone in Black-tailed Prairie Dogs (*Cynomys ludovicianus*). Unpublished study performed by National Wildlife Research Center, Fort Collins, CO. Laboratory Project No. QA-1446. Study sponsored by LiphaTech, Inc., Milwaukee, WI. Study initiated June 15, 2007 and submitted January 16, 2008.

This study was classified as Supplemental under the Guideline Number 850.2400 (Wild Mammal Toxicity). The study resulted in an estimated LD_{50} = 1.94 mg ai/kg-bwt with 95% confidence intervals of (1.46, 5.77). The primary reasons for the supplemental classification are listed below:

1. Age of the test organisms was not provided.
2. Pre-test health (including mortality) of the test population was not provided.
3. Raw data (on an individual animal basis) including weight, food consumption, sublethal effects, time to mortality, and behavior were not provided.

4. Environmental conditions during acclimation were different then environmental conditions under test.
5. For chemicals with this mode of action, gross necropsies should be conducted on all mortalities, as well as on all surviving animals, at the conclusion of the test. No necropsy reports were included in the study report.

Data Evaluation Report on the Acute Oral Toxicity of Chlorophacinone to Black-tailed Prairie Dogs (*Cynomys ludovicianus*)

PMRA Submission Number {.....} EPA MRID Number 473336-01

Data Requirement:	PMRA Data Code	{.....}
	EPA DP Barcode	N/A
	OECD Data Point	{.....}
	EPA MRID	473336-01
	EPA Guideline	850.2400

Test material: Chlorophacinone Technical **Purity:** 99.4%
Common name Chlorophacinone
Chemical name: IUPAC: 2-[(*RS*)-2-(4-chlorophenyl)-2-phenylacetyl]indan-1,3-dione
CAS name: 2-[2-(4-chlorophenyl)phenylacetyl]-1*H*-indene-1,3(2*H*)-dione
CAS No.: 28772-56-7 (reported on p. 12 of 86); 3691-35-8 (reported on p. 70 of 86)
Synonyms: Rozol Rodenticide

Primary Reviewer: Christie E. Padova **Signature:** Christie E. Padova
Staff Scientist, Dynamac Corporation **Date:** 05/05/08

Secondary Reviewer: Teri S. Myers **Signature:**
Senior Scientist, Cambridge Environmental Inc. **Date:** 05/16/08 Teri S Myers

Primary Reviewer(s): Christine Hartless **Date:** 02-02-12
EPA/OPP/EFED/ERB 2 2-2-12

Secondary Reviewer(s): Kristina Garber **Date:** 02-02-12
EPA/OPP/EFED/ERB 2

Reference/Submission No.: {.....}

Company Code	{.....}	[For PMRA]
Active Code	{.....}	[For PMRA]
Use Site Category	{.....}	[For PMRA]
EPA PC Code	067707	

Date Evaluation Completed: 02-01-12

CITATION: Yoder, C.A. 2008. Acute Oral Toxicity (LD50) of Chlorophacinone in Black-tailed Prairie Dogs (*Cynomys ludovicianus*). Unpublished study performed by National Wildlife Research Center, Fort Collins, CO. Laboratory Project No. QA-1446. Study sponsored by LiphaTech, Inc., Milwaukee, WI. Study initiated June 15, 2007 and submitted January 16, 2008.

EXECUTIVE SUMMARY:

The acute oral toxicity of chlorophacinone to wild-caught, ≥1 year old black-tailed prairie dogs (*Cynomys ludovicianus*) was assessed over 22 days. Chlorophacinone was administered to the prairie dogs by gavage at nominal levels of 0 (vehicle control), 0.253, 0.6867, 1.127, 1.56, and 2.0 mg/kg bw. Mean-measured chlorophacinone concentrations were <0.0035 (<LOD, control), 0.254, 0.757, 1.21, 1.71, and 2.12 mg ai/kg bw. The 22-day acute oral LD_{50} (with 95% C.I.) was 1.94 (1.46-5.77) mg ai/kg bw. The 22-day NOAEL for mortality was 0.757 mg ai/kg bw. The NOAEL for clinical signs could not be determined based on data reporting methods in study report.

Non-linear, delayed-response mortality was observed. All mortalities occurred between days 9 and 20 after dosing. Cumulative mortality was 0% in the control through measured 0.757 mg ai/kg bw levels, and 50, 20, and 60% in the measured 1.21, 1.71, and 2.12 mg ai/kg bw levels, respectively.

Most animals were symptomatic for at least 24 hours prior to death. Animals that eventually died exhibited greater incidences (compared to surviving animals) of reduced reaction to external stimuli, reduced appetite, lethargy, hunched posture, comatose state, coldness to touch, reduced grooming practice, dull/closed/swollen eyes, reduced fecal production, bloody feces, and external bleeding.

No treatment-related effects on body weight or food consumption were observed. However, average body weights of surviving animals declined over time in all test groups including the control.

This toxicity study is classified as supplemental and does not satisfy the requirements for a Wild Mammal Acute Toxicity test OPPTS 850.2400. It is classified as **'supplemental'** because:

- Age of the test organisms was not provided other than stating it was presumed all animals were ≥1 yr old. The study protocol (page 57 of 86) stated that only animals meeting one of the following conditions were collected from the field:
  - >600g non-lactating females or
  - >700 g males.

  The study report stated that no animals below 600 g and no nursing females were use for the study.
- Pre-test health (including mortality) of the test population was not provided.
- Raw data (on an individual animal basis) including weight, food consumption, sublethal effects, time to mortality, and behavior were not provided.
- Environmental conditions during acclimation were different then environmental conditions under test. During the holding period, animals were housed individually outside in 2' x 1.5' x 1' or 1.5' x 1.5' x 1' Tomahawk traps partially covered with burlap and with a PVC pipe as a hide for each animal. Additional information regarding the holding period (*e.g.*, food, temperature, humidity, weather conditions, frequency of visual check and handling, mortality, weight changes) was not provided in the study report. During the study period, animals were housed individually in 2' x 2' x 3' stainless steel cages in one of two rooms with 12L:12D light schedule, 60-70°F, and ambient humidity conditions.
- Gross necropsies were not conducted on test animals.
- There is uncertainty in the LD50 value because 1) it is close to the highest test dose, where there was only 60% mortality and 2) the 95% confidence interval extends beyond the highest test concentration.

Results Synopsis

Test Organism Size/Age (Mean Weight):	≥ 1 year old; group mean body weights of 876.50 to 991.00 g (combined sexes)
LD_{50}: 1.94 mg ai/kg bw	95% C.I.: 1.46-5.77 mg ai/kg bw

Probit slope: 3.45 95% C.I.: 0.80-6.1
NOAEL (visually determined based on mortality): 0.757 mg ai/kg bw
NOAEL for clinical signs could not be determined based on data reporting methods in study report.
Endpoint(s) Affected: mortality and clinical signs of toxicity

I. MATERIALS AND METHODS:

GUIDELINE FOLLOWED: The study protocol was based on procedures outlined in the U.S. EPA Ecological Effects Test Guidelines OPPTS No. 850.2400 (1996). Deviations from this guideline included:

1. Age of the test organisms was not provided.
2. Pre-test health (including mortality) of the test population was not provided.
3. Raw data (on an individual animal basis) including weight, food consumption, sublethal effects, time to mortality, and behavior were not provided.
4. Environmental conditions during acclimation were different then environmental conditions under test.

Although not specifically listed in 850.2400, for chemicals with this mode of action, gross necropsies should be conducted on all mortalities, as well as on all surviving animals, at the conclusion of the test. No necropsy reports were included in the study report.

These deviations result in a supplemental classification.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

A. MATERIALS:

1. Test material Chlorophacinone technical

Description: Pale yellow powder

Lot No./Batch No. : 520701

Purity: 99.4%

Stability of compound under test conditions: Sub-samples (three) from each prepared dosing stock solution (at 0, 0.253, 0.6867, 1.127, 1.5600, and 2 mg ai/mL) were collected and analyzed. Recoveries averaged 0.000 ± 0.000, 0.254 ± 0.009, 0.757 ± 0.087, 1.21 ± 0.05, 1.71 ± 0.13, and 2.12 ± 0.06 mg ai/mL, respectively, ranging from 100-110% of nominal.
(OPPTS guidance does not address analysis of the dosing solutions.)

Storage conditions of test chemicals: Not reported

Physicochemical properties of Chlorophacinone.

Parameter	Values	Comments

Parameter	Values	Comments
Water solubility at 20°C	Negligible	
Vapor pressure	Not reported	
UV absorption	Not reported	
pKa	Not reported	
Kow	Not reported	

(OECD recommends water solubility, stability in water and light, pKa, Pow, and vapor pressure of test compound)

2. Test Organism:

Species (common and scientific names): Black-tailed prairie dog (*Cynomys ludovicianus*)

Age at study initiation: ≥1 year

Weight at study initiation (mean and range): Group means of 876.50 to 991.00 g (combined sexes; individual body weight data not reported)

Source: Wild-captured near Kersey, CO and Boulder County, CO

B. STUDY DESIGN:

1. Experimental Conditions

a. Range-finding study: A 21-day range-finding study was conducted from July 3-24, 2007 with two prairie dogs (one per sex) per level at target dosages of 0.25, 0.5, 1, 2, and 4 mg/kg bw. Chlorophacinone concentrations in the propylene glycol gavage solutions were within 10% of the stated concentration. No mortality occurred in the 0.25 mg/kg bw group, 50% mortality occurred in the 1 mg/kg bw group, and 100% mortality occurred in the 0.5, 2, and 4 mg/kg bw groups. The registrant-estimated LD_{50} was 0.49 mg/kg bw.

b. Definitive study

Table 1: Experimental Parameters

Parameter	Details	Remarks
		Criteria

Parameter	Details	Remarks *Criteria*
Acclimation Period: Conditions: (same as test or not) Feeding: Health: (any mortality observed)	14 days Prior to testing, the prairie dogs were housed outdoors, where they were subject to ambient light and temperatures. During testing, they were housed indoors under controlled lighting and temperature. Loose grass hay, timothy hay cubes, apples, and carrots were provided for feed throughout the test. Not reported	Only non-nursing females and animals ≥600 g were used for testing. Animals were dusted with a pyrethrin-based flea powder upon arrival at the National Wildlife Research Center and at the end of the quarantine period.
Pen size and construction materials	2' x 2' x 3' stainless steel cages A water bowl and a length of PVC pipe (as a hide) was provided for each animal.	
Test duration	21 days	
Dose preparation	Dispersed in propylene glycol; concentrations were confirmed using HPLC	

Parameter	Details	Remarks *Criteria*
Mode of dose administration	Gavage	
Dose levels target (in terms of bw): Nominal (dosing solutions): Measured (dosing solutions)	0 (vehicle control), 0.25, 0.6875, 1.125, 1.5625, and 2 mg ai/kg bw 0 (vehicle control), 0.253, 0.6867, 1.127, 1.5600, and 2.0 mg ai/mL dosing solution <0.0035 (<LOD, control), 0.254, 0.757, 1.21, 1.71, and 2.12 mg ai/mL dosing solution	Dosing volumes were approximately 1 mL (adjusted for bw) and the body weight of the prairie dogs was approximately 1 kg, so that the concentrations of ai in the dosing solutions and the amount administered in terms of bw were essentially identical.
Solvent/vehicle, if used type: amount/bw:	Propylene glycol 1 mL/kg bw (approx. 0.1% of bw)	
Number of birds per groups/treatment for negative control: for solvent/vehicle control: for treated:	N/A 10 (5 per sex) 10 (5 per sex)	
No. of feed withholding days before dosing	≥17 hours	
Test conditions Temperature: Relative humidity: Photoperiod:	60-70°F Ambient 12 hours light/12 hours dark	Animals were equally divided between two test rooms.
Reference chemical, if used name: concentrations tested:	None tested	

2. Observations:

Table 2: Observations

Criteria	Details	Remarks *Criteria*
Parameters measured (mortality/individual body weight at test initiation and termination/ mean feed consumption/ others)	Mortality Clinical signs of toxicity Food consumption Body weight	
Indicate if the test material was regurgitated	None indicated	
Groups on which necropsies were performed	None	
Observation intervals	Animals were observed immediately after gavage for signs of regurgitation or aspiration, and 2 to 3 times daily thereafter for signs of toxicity. Body weights were measured on days 0, 7, 14, and 22. Average food consumption (apples and carrots only) was determined daily, and reported for days 1-7, 8-14, and 15-22.	
Were raw data included?	No, summarized data tables were provided.	

II. RESULTS AND DISCUSSION:

A. MORTALITY:

Non-linear mortality responses were observed, and animals died between days 9 and 20 of the test (delayed response). Cumulative mortality was 0% in the control through measured 0.757 mg ai/kg bw levels, and 50, 20, and 60% in the measured 1.21, 1.71, and 2.12 mg ai/kg bw levels, respectively. The 22-day acute oral LD_{50} (with 95% C.I.) was reported by the study author to be 1.8 (1.36-5.44) mg ai/kg bw (based on target concentrations). The NOAEL for mortality was visually determined as 0.757 mg ai/kg bw. The NOAEL for clinical signs could not be determined based on data reporting methods in study report.

The study author suggested that mortality exhibited two distinct peaks. The majority of deaths occurred between days 9-14 of the study. A second, smaller peak of deaths occurred between days 17-20 of the study. In addition, there were two animals still alive at the end of the study that had eaten very little for a week, and appeared to be ill. The study author suggested that some of the variability may be explained by genetic variability in the CYP2C9 (cytochrome P450 2C9) and VKORC1 (vitamin K epoxide reductase complex, subunit 1) genes. Specifically, mutations of the CYP2C9 gene affect metabolism of anticoagulants, whereas mutations of the VKORC1 gene affect the potency of anticoagulants.

Table 3: Effect of Chlorophacinone on Mortality of Black-tailed Prairie Dogs (*Cynomys ludovicianus*).

Treatment, Target and (Measured*) Concn. mg ai/kg bw		No. of Prairie Dogs	Cumulative Mortality				
			Day 7	day 10	day 13	day 17	day 22
Vehicle control		10	0	0	0	0	0
0.25 (0.254)		10	0	0	0	0	0
0.6875 (0.757)		10	0	0	0	0	0
1.125 (1.21)		10	0	2	5	5	5
1.5625 (1.71)		10	0	0	0	0	2
2.0 (2.12)		10	0	1	3	6	6
NOAEL		0.6875 mg ai/kg bw					
LD_{50} (with 95% C.I.)		1.8 (1.35-5.29) mg ai/kg bw, based on target concentrations					
Reference chemical	mortality	N/A					
	LD_{50}	N/A					
	NOAEL	N/A					

*Measured concentrations of the dosing solutions were in units of mg ai/mL; however, because the dosing volume was 1 mL/kg bw, target and measured dosing solution concentration units are similar and both can be expressed as mg ai/kg bw.

B. SUB-LETHAL TOXICITY ENDPOINTS:

Although two animals exhibited no symptoms prior to death, most animals were symptomatic for at least 24 hours prior to death. Animals that eventually died exhibited (compared to surviving animals) reduced reaction to external stimuli (*i.e.*, reaction to cage entry), reduced appetite, and increased incidences of lethargy, hunched

posture, comatose state, and cold to the touch. Grooming practice decreased in animals that eventually died, and eyes appeared dull, semi-closed or closed, or swollen 23.2% of the time. Fecal production was also reduced in animals that eventually died. Blood was found in the feces of animals that survived 3.6% of the time compared to 9.5% of the time for animals that eventually died. In addition, animals that survived exhibited external bleeding 8.2% of the time, compared to 26.9% for animals that eventually died.

No treatment-related effects on body weight were observed. Body weights did not differ between the test rooms or among groups, but tended to decrease over time at all levels (including controls), despite offering increased amounts of food. It was reported that as prairie dogs are social animals, it is possible that the stress of being moved indoors into cages where the animals could not easily observed their neighbors may have contributed to the weight loss. Because weight loss also occurred in the control group, it was unlikely that chlorophacinone played a role.

Consumption of carrots and apples varied among study days, but did not differ among the groups. Decreased food consumption tended to occur when animals became ill prior to death. Consumption of carrots did not differ between rooms, but consumption of apples did vary between rooms ($p=0.0424$). The difference in apple consumption between the rooms was only marginally significant, and likely was not biologically significant. The standardized amount of apples eaten over the entire study period for the two rooms was 0.077 ± 0.003 and 0.069 ± 0.003 g apples/g bw.

Table 4: Sub-lethal Effect of Chlorophacinone on Black-tailed Prairie Dogs (*Cynomys ludovicianus*).

		Mean Body Weight, g			
Treatment, Target and (Measured*) Concn. mg ai/kg bw		**Day 0**	**Day 7**	**Day 14**	**Day 21**
Vehicle control		991.00	971.50	942.00	798.50
0.25 (0.254)		876.50	865.00	852.00	725.00
0.6875 (0.757)		940.00	918.00	883.00	750.50
1.125 (1.21)		927.50	907.00	799.00	677.00
1.5625 (1.71)		946.00	920.00	906.50	836.88
2.0 (2.12)		947.00	929.00	850.89	698.75
NOAEL		2.0 mg ai/kg bw		2.0 mg ai/kg bw	
EC_{50}		Not determined		Not determined	
Reference chemical	effect: NOAEL: LD_{50}:	N/A			

*Measured concentrations of the dosing solutions were in units of mg ai/mL; however, because the dosing volume was 1 mL/kg bw, target and measured dosing solution concentration units are similar and both can be expressed as mg ai/kg bw.

C. REPORTED STATISTICS:

Food consumption was standardized by dividing the grams of food consumed for each animal each day by that animal's body weight. Animal body weights were only included for analysis of differences in weights among groups if they were alive on the date of weighing. Animals found dead on the day of weighing were included in the data for that day. Standardized food weights and weekly body weights were analyzed as a mixed effects model (PROC MIXED, SAS Institute Inc.). Means separations were carried out using PDMIX800 (Saxton, 1998).

Probit analysis was used to determined an LD_{50} (PROC PROBIT, SAS Institute) and associated confidence limits. Data were analyzed using raw data and the natural log of dose. The study author based these calculations on the target concentrations.

Clinical signs of toxicity were assigned a numeric scale of severity, with higher numbers associated with greater pain or distress. Data was split into two groups: animals that survived and those that died. Observations in each group were pooled across the entire study period, and frequencies were determined for each level of each parameter.

D. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: The reviewer verified the LD_{50} using the probit method via Toxanal statistical software. The reviewer based toxicity calculations on the measured dosing solution concentrations, which could be expressed in terms of body weight because the dosing volume was 1 mL/kg bw.

The NOAEC could be visually verified, based on mortality data. Individual animal data were not provided for body weight or food consumption. NOAEL for clinical signs could not be determined based on data reporting methods in study report.

LD_{50}: 1.94 mg ai/kg bw 95% C.I.: 1.46-5.77 mg ai/kg bw
Probit slope: 3.45 95% C.I.: 0.80-6.1
NOAEL (visually based on mortality): 0.757 mg ai/kg bw
Endpoint(s) Affected: mortality and clinical signs of toxicity

E. STUDY DEFICIENCIES:

1. Age of the test organisms was not provided.
2. Pre-test health (including mortality) of the test population was not provided.
3. Raw data (on an individual animal basis) including weight, food consumption, sublethal effects, time to mortality, and behavior were not provided.
4. Environmental conditions during acclimation were different then environmental conditions under test.
5. Gross necropsies were not conducted on test animals.

F. REVIEWER'S COMMENTS:

The reviewer's conclusions agreed with the study author's, with the exception that the reviewer expressed results in terms of the measured dosing concentrations. The study authors used target concentrations because chlorophacinone concentrations were within 10% of the stated concentrations. The reviewer's results are reported in the Executive Summary and Conclusions sections.

It was reported that prairie dogs tended to throw loose hay out of their cages onto the floor making an accurate assessment of consumption impossible. In addition, the amount of hay weighed back in some cages was more

than what was offered because hay fell down from the cage above. Likewise, an accurate assessment of consumption of timothy hay cubes was not possible. Therefore, only consumption of apples and carrots were used for statistical analysis by the study author; replicate data were not provided for the reviewer's verification of these results.

The study author reported that apples, carrots, and timothy hay (loose or cubes) was provided to the animals on test. These foods were chosen as an alternative to the typical feed for caged prairie dogs (rodent blocks or alfalfa cubes) to reduce the vitamin K intake relative to the typical caged rodent diet. The study author stated that the level of vitamin K in the provided diet would be comparable to the vitamin K intake prairie dogs in the wild may intake. This USDA reference provides typical vitamin K concentrations in many foodstuffs: http://www.nal.usda.gov/fnic/foodcomp/Data/SR17/wtrank/sr17w430.pdf, confirming that carrots and apples have lower levels of vitamin K than many of the leafy green vegetables (most comparable to alfalfa cubes). No evidence was presented by the study author to confirm that the levels of vitamin K in the provided diet was similar to the levels of vitamin K in the diet of wild prairie dogs. Black-tailed prairie dogs are selectively herbivorous [1] with favorite foods in the summer to include wheatgrass *(Agopyron* sp.), grama *(Bouteloua* sp.), buffalo grass *(Bromus* sp.), scarlet globemallow, and rabbitbrush *(Chrysothamnus* sp.; Koford, 1958; Summers and Linder, 1978) and preferred forage in the winter to include prickly pear cactus *(Opuntia* sp.), thistle *(Cirsium* sp.), and underground roots. This study was conducted during the summer months when grasses, not fruits and vegetables, are the major component of the prairie dog's natural diet. The inclusion of carrots and apples may represent a significant deviation from the naturally occurring foodstuffs of the prairie dog. The level of effect that the provided diet had on mediating or increasing the toxic effect of chlorophacinone is an uncertainty.

The study author's discussion suggested that the animals were stressed with their move indoors at the start of the testing period:

> "Decreased body weights occurred with time in all treatment groups, including the control group, despite offering increased amounts of food. The amount of food offered to each prairie dog was significantly more than the amount offered to the prairie dogs during the quarantine period. Most animals gained weight during the quarantine period. Because prairie dogs are social animals, it is possible that the stress of being moved indoors into cages where the animals could not easily observe their neighbors may have contributed to the weight loss. Because weight loss also occurred in the control group, it is unlikely chlorophacinone played a role." (page 19 of 86)

The study author concluded that it is unlikely that he weight loss impacted the estimate of the LD50. There were no significant differences in weight loss across test groups, and no control animals died. Because information on sublethal effects was not reported on an individual basis or a test group basis, the reviewer cannot determine the likelihood of the environmental change and weight loss on the presence and prevalence sub-lethal effects.

Lack of gross necropsy results for all tested individuals is an additional uncertainty. External bleeding and bloody stools was noted in several individuals for both mortalities and survivors. It is unknown whether individuals surviving till the end of the study were experiencing internal bleeding that would have precluded survival in the wild.

Animals were dusted with a pyrethrin-based flea powder upon arrival at the National Wildlife Research Center and at the end of the quarantine period. Given that pyrethroids do not generally impact mammals on an acute exposure basis, and that the controls were also treated with flea powder with no reported ill-effects, it is unlikely that the pesticide treatment (flea powder) would impact the LD50 estimate.

---

1 J. L. Hoogland, *Cynomys ludovicianus*. Mammalian Species No. 535, pp. 1-10, December 1996 by the American Society of Mammalogists

In-life dates for the definitive study were July 26 – August 16, 2007.

G. CONCLUSIONS:

This study is classified as Supplemental. Treatment-related mortality occurred at the ≥1.21 mg ai/kg bw dose levels; the 22-day LD_{50} (with 95% C.I.) was 1.94 (1.46-5.77) mg ai/kg bw. Clinical effects observed to a greater degree in animals that eventually died during the study included reduced reaction to external stimuli, reduced appetite, lethargy, hunched posture, comatose state, cold to the touch, reduced grooming, dull/closed/swollen eyes, reduced feces, bloody feces, and external bleeding. No clear treatment-related effects on food consumption or body weights were observed.

LD_{50}: 1.94 mg ai/kg bw 95% C.I.: 1.46-5.77 mg ai/kg bw
Probit slope: 3.45 95% C.I.: 0.80-6.1
NOAEL (visually based on mortality): 0.757 mg ai/kg bw
NOAEL for clinical signs could not be determined based on data reporting methods in study report.
Endpoint(s) Affected: mortality and clinical signs of toxicity

III. REFERENCES:

Andelt, W.F., and S.N. Hopper. 1998. Managing prairie dogs. Colorado State University Cooperative Extension Bulletin Number 6.506, Fort Collins.

Arjo, W.J., and D.L. Nolte. 2004. Assessing the efficacy of registered underground baiting products for mountain beaver (*Aplodontia rufa*) control. Crop Protection 23:425-430.

Barnes, A.M. 1982. Surveillance and control of bubonic plague in the United States. Symposia of the Zoological Society of London 50:237-270.

Byron, K.A., and A.E. Dear. 2007. Genotype and adverse drug reactions to warfarin. Medical Journal of Australia 187:61-62.

Cully, J.F., Jr. 1997. Growth and life-history changes in Gunnison's prairie dogs after a plague epizootic. Journal of Mammalogy 78:146-157.

Fagerstone, K.A. 1982. A review of prairie dog diet and its variability among animals and colonies. Proceedings of the Great Plains Wildlife Damage Control Workshop 5:178-184.

Franklin, W.L., and M.G. Garrett. 1989. Nonlethal control of prairie dog colony expansion with visual barriers. Wildlife Society Bulletin 17:426-430.

Hadler, M.R., and A.P. Buckle. 1992. Forty-five years of anticoagulant rodenticides – past, present, and future trends. Proceedings of the Vertebrate Pest Conference 15:149-155.

Haroon, Y., and P.V. Hauschka. 1983. Application of high-performance liquid chromatography to assay phylloquinone (vitamin K1) in rat liver. Journal of Lipid Research 24:481-484.

Hoogland, J.L. 1995. The black-tailed prairie dog: Social life of a burrowing mammal. University of Chicago Press, Chicago.

Hygnstrom, S.E., and D.R. Virchow. 1994. Prairie dogs. Pages B-85 to B-96 *in* S.E. Hygnstrom, R.M. Timm, and G.E. Larson, editors. Prevention and Control of Wildlife Damage. University of Nebraska, Great Plains

Agricultural Council, USDA/APHIS/WS.

International Programme on Chemical Safety. Chlorophacinone. Data sheets on pesticides No. 62. Accessed on January 4, 2007 at the following website: http://www.inchem.org/documents/pds/pds/pest62.e.htm.

Menkens, G.E., Jr., and S.H. Anderson. 1991. Population dynamics of white-tailed prairie dogs during an epizootic of sylvatic plague. Journal of Mammalogy 72:328-331.

Miller, B., *et al.* 2000. the role of prairie dogs as a keystone species: Response to Stapp. Conservation Biology 14:318-321.

Pelz, H-J., *et al.* 2005. The genetic basis of resistance to anticoagulants in rodents. Genetics 170:1839-1847.

Robinette, K.W., W.F. Andelt, and K.P. Burnham. 1995. Effect of group size on survival of relocated prairie dogs. Journal of Wildlife Management 59:867-874.

Saxton, A.M. 1998. A macro for converting mean separation output to letter groupings in PROC MIXED. Proceedings SAS Users Group International 23:1243-1246.

Sconce, E.A., *et al.* 2005. The impact of *CYP2C9* and *VKORC1* genetic polymorphism and patient characteristics upon warfarin dose requirements: Proposal for a new dosing regimen. Blood 106:2329-2333.

Silverman, R.B. 1980. A model for the molecular mechanism of anticoagulant activity of 3-substituted 4-hydroxycourmarins. Journal of the American Chemical Society 102:5421-5423.

Timm, R.M. 1994. Anticoagulants. Pages G26-G29 *in* Prevention and Control of Wildlife Damage. Hyhnstrom, S.E., R.M. Timm, and G.E. Larson, eds. University of Nebraska Cooperative Extension, Lincoln, Nebraska.

Watt, B.E., *et al.* 2005. Anticoagulant rodenticides. Toxicological Reviews 24:259-269.

Zinn, H.C., and W.F. Andelt. 1999. Attitudes of Fort Collins, Colorado, residents toward prairie dogs. Wildlife Society Bulleting 27:1098-1106.

APPENDIX I. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:

christine rozol prairie dog

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
2.12	10	6	60.00001	37.69531
1.71	10	2	20	5.46875
1.21	10	5	50	62.30469
.757	10	0	0	9.765625E-02
.254	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT .757 AND +INFINITY CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 2.013327

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
1	1.25215	2.013327	1.626061	+INFINITY

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
5	.5909886	1	7.972473E-02

SLOPE = 3.449044
95 PERCENT CONFIDENCE LIMITS = .7975643 AND 6.100523

INTERCEPT=-.995549

LC50 = 1.94377
95 PERCENT CONFIDENCE LIMITS = 1.460883 AND 5.768695

LC25 = 1.239035
95 PERCENT CONFIDENCE LIMITS = .5558989 AND 1.676615

LC10 = .8261591
95 PERCENT CONFIDENCE LIMITS = .1107309 AND 1.159983

LC05 = .6482315
95 PERCENT CONFIDENCE LIMITS = 3.976897E-02 AND .9865338
****

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

DEC 13 2011

Scott Larson
United States Fish and Wildlife Service
South Dakota Field Office
420 South Garfield Ave., Suite 400
Pierre, South Dakota 57501

Thomas Schmit
Liphatech, Inc.
3600 W. Elm Street
Milwaukee, Wisconsin 53209

Dear Mr. Larson and Mr. Schmit:

The purpose of this letter is to ensure that the administrative record reflects the work of the Environmental Protection Agency (EPA), the registrant, Liphatech, and the U.S. Fish and Wildlife Service (FWS) to implement specific conservation measures intended to avoid and minimize impacts to listed species from the use of Rozol on black-tailed prairie dogs (*Cynomys ludovicianus*). This consultation addresses the use of Rozol Prairie Dog Bait (EPA Reg. No 7173-286) containing the active ingredient chlorophacinone, which was registered in May 2009 under Section 3 of FIFRA for use to control black-tailed prairie dogs in 10 states: Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming. Pursuant to court order, Rozol is not currently registered for use in Montana, New Mexico, North Dakota, or South Dakota. http://www.epa.gov/pesticides/regulating/rozol.html. However, except as noted below, the parties agree to maintain all 10 states in the scope of consultation.

Based on discussions between EPA, FWS, and Liphatech, the parties agree to modify the scope of consultation to incorporate specific conservation measures for the black-footed ferret (*Mustela nigripes*), grizzly bear (*Ursus arctos horribilis*), Preble's meadow jumping mouse (*Zapus hudsonius preblei*), and five species found in New Mexico: the Mexican gray wolf (*Canis lupus baileyi*), the Mexican spotted owl (*Strix occidentalis lucida*), the Chiricahua leopard frog (*Lithobates [=Rana] chiricahuensis*), the jaguar (*Panthera onca*), and the New Mexican ridge-nosed rattlesnake (*Crotalus willardi*). The proposed conservation measures that EPA, Liphatech, and FWS agree should be assumed for purposes of consultation are provided in the Enclosure to this letter. EPA understands that Liphatech intends to submit a voluntary amendment to its FIFRA registration to match the new scope of consultation.

EPA believes that the agreed upon mitigation measures will be instrumental in achieving successful formal Section 7 consultation and result in valuable protections for listed species that co-occur within the 10 state area where Rozol can be used to control black-tailed prairie dogs.

Enclosure

Sincerely,

John Hebert
Registration Division (7505P)
Office of Pesticide Programs

cc: Donald Brady
Anita Pease
Meredith Laws
Lois Rossi
Michael Thabault
Nancy Golden
Sarena Selbo

Enclosure
Specific Conservation Measures

EPA, Liphatech, and FWS have agreed to modify the scope of consultation to assume the addition of the following specific mitigation measures for Rozol Prairie Dog Bait ("Rozol") for the black-footed ferret (*Mustela nigripes*), grizzly bear (*Ursus arctos horribilis*), Preble's meadow jumping mouse (*Zapus hudsonius preblei*), and five species found in New Mexico: the Mexican gray wolf (*Canis lupus baileyi*), the Mexican spotted owl (*Strix occidentalis lucida*), the Chiricahua leopard frog (*Lithobates [=Rana] chiricahuensis*), the jaguar (*Panthera onca*), and the New Mexican ridge-nosed rattlesnake (*Crotalus willardi*).

Black-footed ferret (*Mustela nigripes*)

FWS provided EPA with a map of 19 black-footed ferret reintroduction sites (Figure 1: BFF Reintro Map 9.21.11.pdf). This map served as an initial starting point to discuss specific conservation measures for the black-footed ferret. Each of the reintroduction sites as they are identified on the map are discussed below.

1. Shirley Basin, WY: Not applicable. This site only has white-tailed prairie dogs and Rozol may not be used to control white-tailed prairie dogs; therefore, no restriction on Rozol use to control black-tailed prairie dogs is necessary.
2. Badlands National Park, SD: Rozol use would be prohibited throughout the Badlands National Park. FWS provided a shapefile to EPA to define this area (see Figure 2). The following files were provided:
   Badlbndp.prj
   Badlbndp.dbf
   Badlbndp.shx
   Badlbndp.shp
   Badlbndp.sbx
   Badlbndp.sbn
3. UL Bend National Wildlife Refuge, MT: Rozol use would be prohibited throughout the UL Bend National Wildlife Refuge. FWS provided a shapefile to EPA to define this area (see Figure 3). The following files were provided:
   ULBbnd.dbf
   ULBbnd.prj
   ULBbnd.sbn
   ULBbnd.sbx
   ULBbnd.shp
   ULBbnd.shp.xml
   ULBbnd.shx
4. Conata Basin, SD: Rozol use would be prohibited throughout the Conata Basin. FWS provided a shapefile to EPA to define this area (see Figure 4). The following files were provided:
   Conata_basin_bff_area.shx
   Conata_basin_bff_area.dbf
   Conata_basin_bff_area.prj
   Conata_basin_bff_area.sbn
   Conata_basin_bff_area.sbx
   Conata_basin_bff_area.shp
5. Aubrey Valley, AZ: Not applicable. This site is in Arizona, which is outside the 10-state scope of consultation.
6. Ft. Belknap Indian Reservation, MT: Rozol use would be prohibited on Tribal lands within the Ft. Belknap Indian Reservation. FWS provided a shapefile to EPA to define all Indian

Reservations in Montana where black-footed ferrets were reintroduced, including the Ft. Belknap Indian Reservation (see Figure 5). The following files were provided:

MT_reservations.shx
MT_reservations.dbf
MT_reservations.prj
MT_reservations.sbn
MT_reservations.sbx
MT_reservations.shp

7. Coyote Basin, UT: Not applicable. This site is in Utah, which is outside the 10-state scope of consultation. Also, the site only has white-tailed prairie dogs and Rozol may not be used to control white-tailed prairie dogs; therefore, no restriction on Rozol use to control black-tailed prairie dogs is necessary.
8. Cheyenne River Indian Reservation, SD: Rozol use would be prohibited on Tribal lands within the Cheyenne River Indian Reservation. FWS provided a shapefile to EPA to define all Indian Reservations in South Dakota where black-footed ferrets were reintroduced, including the Cheyenne River Indian Reservation (see Figure 6). The following files were provided:

   SD_reservations.shx
   SD_reservations.dbf
   SD_reservations.prj
   SD_reservations.sbn
   SD_reservations.sbx
   SD_reservations.shp

9. Wolf Creek, CO: Not applicable. This site only has white-tailed prairie dogs and Rozol may not be used to control white-tailed prairie dogs; therefore, no restriction on Rozol use to control black-tailed prairie dogs is necessary.
10. BLM 40-complex, MT: Rozol use would be prohibited throughout the BLM 40-complex. FWS provided a shapefile to EPA to define this area (see Figure 7). The following files were provided:

    40Complexarea.shp.xml
    40Complexarea.dbf
    40Complexarea.sbn
    40Complexarea.sbx
    40Complexarea.shp
    40Complexarea.shx
    40Complexarea.prj

11. Janos, Mexico: Not applicable. EPA has no jurisdiction over the use of pesticides in Mexico.
12. Rosebud Indian Reservation, SD: Rozol use would be prohibited on Tribal lands within the Rosebud Indian Reservation. FWS provided a shapefile to EPA to define all Indian Reservations in South Dakota where black-footed ferrets were reintroduced, including the Rosebud Indian Reservation (see Figure 8). The following files were provided:

    SD_reservations.shx
    SD_reservations.dbf
    SD_reservations.prj
    SD_reservations.sbn
    SD_reservations.sbx
    SD_reservations.shp

13. Lower Brule Indian Reservation, SD: Rozol use would be prohibited on Tribal lands within the Lower Brule Indian Reservation. FWS provided a shapefile to EPA to define all Indian Reservations in South Dakota where black-footed ferrets were reintroduced, including the Lower Brule Indian Reservation (see Figure 9). The following files were provided:

    SD_reservations.shx

SD_reservations.dbf
SD_reservations.prj
SD_reservations.sbn
SD_reservations.sbx
SD_reservations.shp

14. Wind Cave National Park, SD: Rozol use would be prohibited throughout Wind Cave National Park. FWS provided a shapefile to EPA to define this area (see Figure 10). The following files were provided:

boundary_line.shx
boundary_line.dbf
boundary_line.prj
boundary_line.sbn
boundary_line.sbx
boundary_line.shp
boundary_line.shp.xml

Custer State Park, SD: Rozol use would be prohibited throughout Custer State Park (see Figure 10).[1] FWS provided a shapefile to EPA to define this area. The following files were provided:

parkbndr83.sbn
parkbndr83.sbx
parkbndr83.shp
parkbndr83.shx
parkbndr83.dbf
parkbndr83.prj

15. Espee Ranch, AZ: Not applicable. This site is in Arizona, which is outside the 10-state scope of consultation.
16. Logan County, KS: Rozol use would be prohibited throughout the area defined by the FWS within Logan County, Kansas. FWS provided a shapefile to EPA to define this area (see Figure 11). The following files were provided:

KS_Ferret_Areas.dbf
KS_Ferret_Areas.prj
KS_Ferret_Areas.sbn
KS_Ferret_Areas.sbx
KS_Ferret_Areas.shp
KS_Ferret_Areas.shx

17. Northern Cheyenne Indian Reservation, MT: Rozol use would be prohibited on Tribal lands within the Northern Cheyenne Indian Reservation. FWS provided a shapefile to EPA to define all Indian Reservation in Montana where black-footed ferrets were reintroduced, including the Northern Cheyenne Indian Reservation (see Figure 12). The following files were provided:

MT_reservations.shx
MT_reservations.dbf
MT_reservations.prj
MT_reservations.sbn
MT_reservations.sbx
MT_reservations.shp

18. Vermejo Park Ranch, NM: Rozol use would be prohibited throughout Vermejo Park Ranch. FWS provided a shapefile to EPA to define this area (see Figure 13). The following files were provided:

[1] FWS suggested including Custer State Park because it is adjacent to Wind Cave National Park on Wind Cave's north boundary. FWS states that some ferrets from the Wind Cave ferret release have moved onto prairie dog colonies in Custer State Park.

boundarypoly.dbf
boundarypoly.sbn
boundarypoly.sbx
boundarypoly.shp
boundarypoly.shx

19. Grasslands National Park, SK Canada: Not applicable. EPA has no jurisdiction over the use of pesticides in Canada.

Grizzly bear (*Ursus arctos horribilis*)

FWS provided a map (Figure 14: 2011 10 20 MISC grizzly bear time restriction map.pdf) and a description of the areas where timing restrictions would apply to the grizzly bear (Rozol Grizzly timing restriction 10.21.11.docx). As a result, EPA will prepare this shapefile. Within the following counties or portions of counties in MT (as indicated below), Rozol use would be limited to the period December 1 through March 15:

Carbon County, MT
Stillwater County, MT – South of I-90
Sweetgrass County, MT – South of I-90
Park County, MT – South of I-90
Gallatin County, MT – South of I-90
Madison County, MT
Powell County, MT
Lewis and Clark County, MT
Cascade County, MT
Teton County, MT
Pondera County, MT
Glacier County, MT
Toole County, MT

Preble's meadow jumping mouse (*Zapus hudsonius preblei*)

FWS provided a map (10-27-2011_PMJM_Rozol_Exclusion_CO_and_WY.pdf) and a shapefile for the area where timing restrictions would apply to the Preble's meadow jumping mouse. Within the specified polygons for Colorado and Wyoming, Rozol use would be limited to the period November 1 through March 15. The following files were provided to define the area (see Figure 15 for Colorado and Figure 16 for Wyoming):

10-27-2011_PMJM_Rozol_Exclusion_Colorado.dbf
10-27-2011_PMJM_Rozol_Exclusion_Colorado.shx
10-27-2011_PMJM_Rozol_Exclusion_Colorado.prj
10-27-2011_PMJM_Rozol_Exclusion_Colorado.sbn
10-27-2011_PMJM_Rozol_Exclusion_Colorado.sbx
10-27-2011_PMJM_Rozol_Exclusion_Colorado.shp

10-27-2011_PMJM_Rozol_Exclusion_Wyoming.shp
10-27-2011_PMJM_Rozol_Exclusion_Wyoming.dbf
10-27-2011_PMJM_Rozol_Exclusion_Wyoming.shx
10-27-2011_PMJM_Rozol_Exclusion_Wyoming.prj
10-27-2011_PMJM_Rozol_Exclusion_Wyoming.sbn
10-27-2011_PMJM_Rozol_Exclusion_Wyoming.sbx

**Five species found in New Mexico: the Mexican gray wolf (*Canis lupus baileyi*), the Mexican spotted owl (*Strix occidentalis lucida*), the Chiricahua leopard frog (*Lithobates [=Rana]*

***chiricahuensis*), the jaguar (*Panthera onca*), and the New Mexican ridge-nosed rattlesnake (*Crotalus willardi*)**

FWS provided a shapefile for the five county area in southwestern New Mexico where Rozol use would be prohibited to protect five listed species including the Mexican gray wolf (*Canis lupus baileyi*), the Mexican spotted owl (*Strix occidentalis lucida*), the Chiricahua leopard frog (*Lithobates [=Rana] chiricahuensis*), the jaguar (*Panthera onca*), and the New Mexican ridge-nosed rattlesnake (*Crotalus willardi*). FWS provided a description of these counties and the species which are located within each county (Justification for New Mexico County Exclusions.docx). Rozol use would be prohibited throughout the following five counties in southwestern New Mexico (see Figure 17):

Catron County, NM
Grant County, NM
Hidalgo County, NM
Sierra County, NM
Socorro County, NM

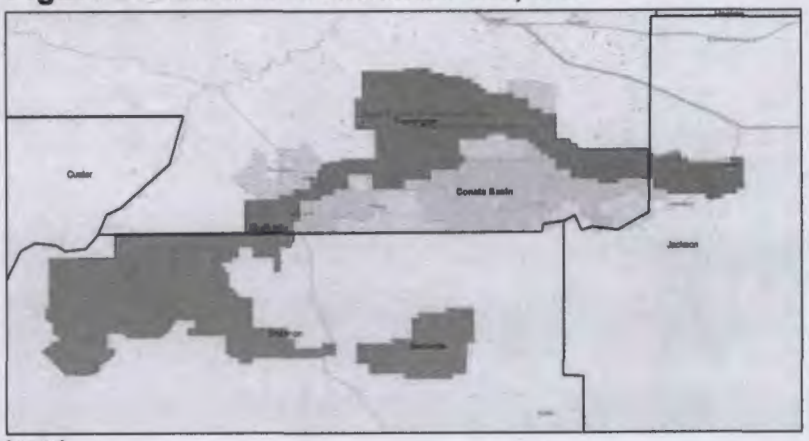
Ferret Reintroduction Sites

Among various prairie dog species

1. Shirley Basin, WY (1991)
2. Badlands NP, SD (1994)
3. UL Bend NWR, MT (1994)
4. Conata Basin, SD (1996)
5. Aubrey Valley, AZ (1996)
6. Ft. Belknap Indian Reservation, MT (1997)
7. Coyote Basin, UT (1999)
8. Cheyenne River Indian Reservation, SD (2000)
9. Wolf Creek, CO (2001)
10. BLM 40-complex, MT (2001)
11. Janos, Mexico (2001)
12. Rosebud Indian Reservation, SD (2004)
13. Lower Brule Indian Reservation, SD (2006)
14. Wind Cave NP, SD (2007)
15. Espee Ranch, AZ (2007)
16. Logan County, KS (2007)
17. Northern Cheyenne Indian Reservation, MT (2008)
18. Vermejo Park Ranch, NM (2008)
19. Grasslands National Park, SK, Canada (2009)

Figure 1: BFF Reintro Map 9.21.11.pdf

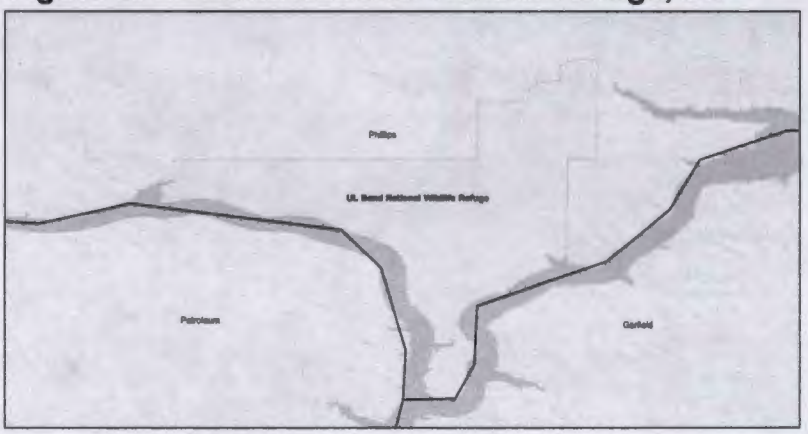
Figure 2. Badlands National Park, SD



Legend

- County Boundary
- Badlands National Park, South Dakota - Rozol use is prohibited within this area.
- Conata Basin, South Dakota - Rozol use is prohibited within this area.

Figure 3. UL Bend National Wildlife Refuge, MT

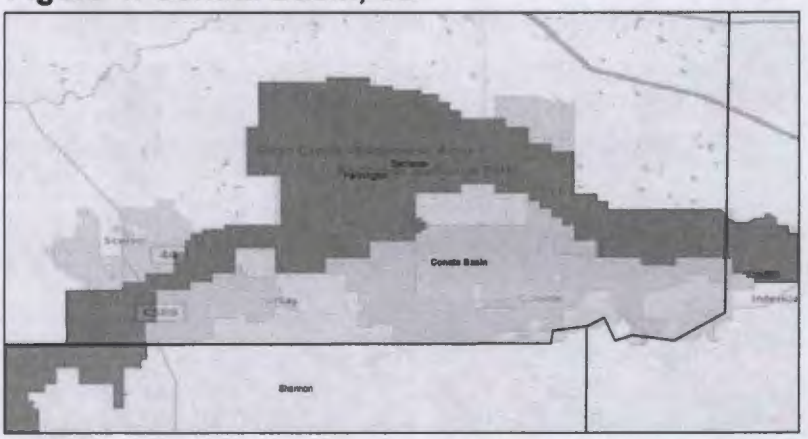


Legend

County Boundary

UL Bend National Wildlife Refuge, Montana - Rozol use is prohibited within this area.

Figure 4. Conata Basin, SD



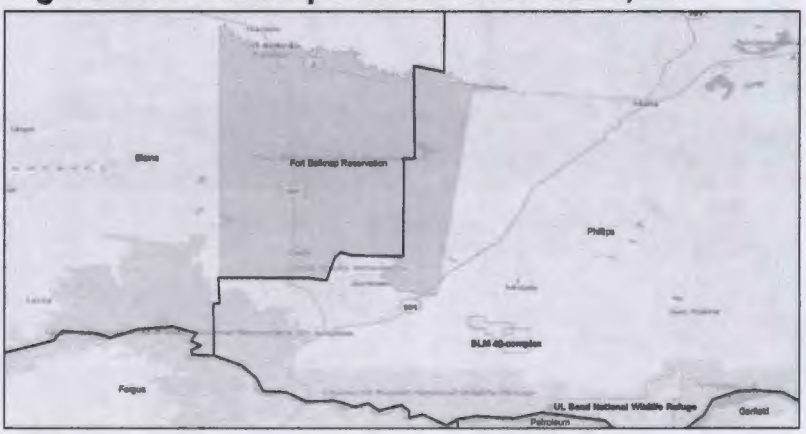
Legend

County Boundary

Conata Basin, South Dakota - Rozol use is prohibited within this area.

Badlands National Park, South Dakota - Rozol use is prohibited within this area.

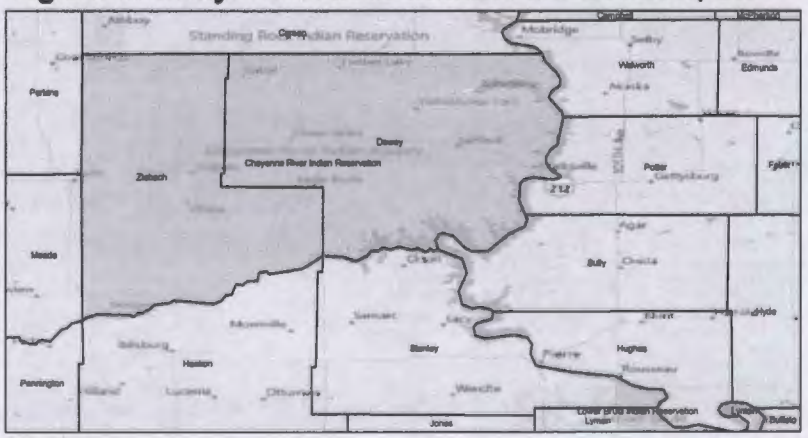
Figure 5. Ft. Belknap Indian Reservation, MT



Legend

- County Boundary
- Montana Indian Reservations (Ft. Belknap Indian Reservation) - Rozol use is prohibited on Tribal lands within the Ft. Belknap Indian Reservation.
- BLM 40-complex, Montana - Rozol use is prohibited within this area.
- UL Bend National Wildlife Refuge, Montana - Rozol use is prohibited within this area.

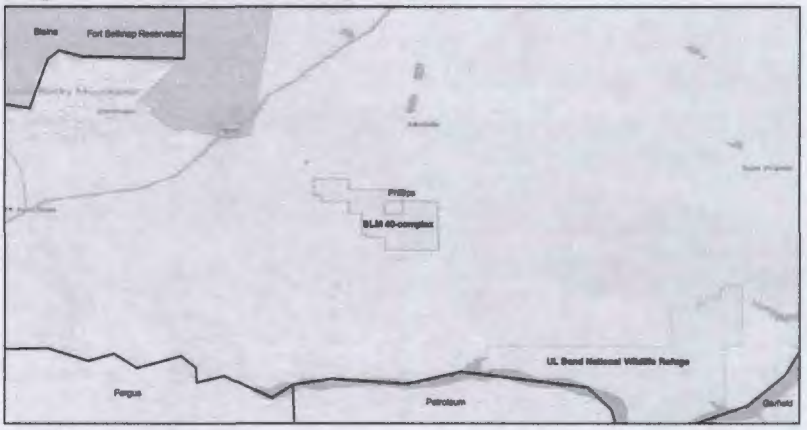
Figure 6. Cheyenne River Indian Reservation, SD



Legend

- County Boundary
- South Dakota Indian Reservations - Rozol use is prohibited on Tribal lands within the Cheyenne River and Lower Brule Indian Reservations.

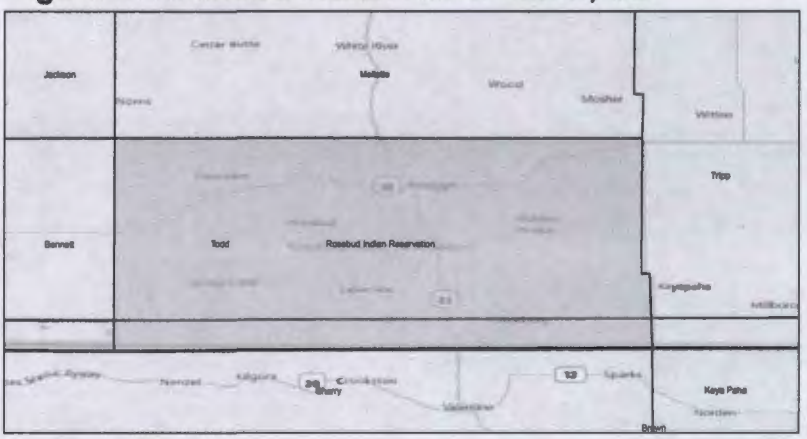
Figure 7. BLM 40-complex, MT



Legend

- County Boundary
- BLM 40-complex, Montana - Rozol use is prohibited within this area.
- UL Bend National Wildlife Refuge, Montana - Rozol use is prohibited within this area.
- Montana Indian Reservations (Ft. Belknap Indian Reservation) - Rozol use is prohibited on Tribal lands within the Ft. Belknap Indian Reservation.

Figure 8. Rosebud Indian Reservation, SD



Legend

- County Boundary
- South Dakota Indian Reservations (Rosebud Indian Reservation) - Rozol use is prohibited on Tribal lands within the Rosebud Indian Reservation.

Figure 9. Lower Brule Indian Reservation, SD

Legend

County Boundary

South Dakota Indian Reservations (Lower Brule Indian Reservation) - Rozol use is prohibited on Tribal lands within the Lower Brule Indian Reservation.

Figure 10. Wind Cave National Park, SD & Custer State Park, SD

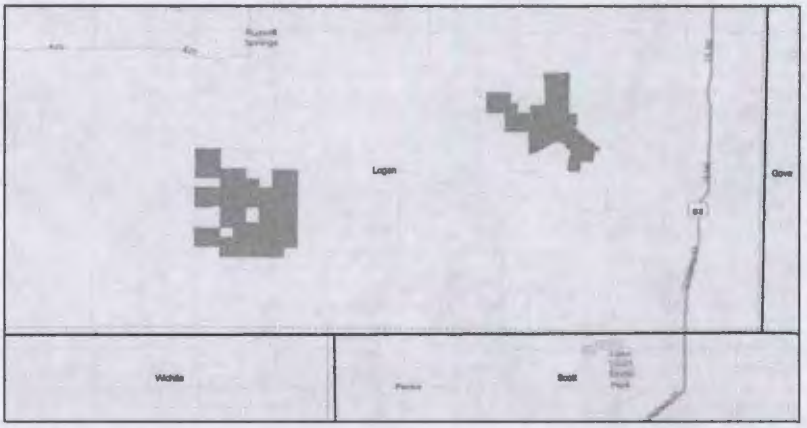
Legend

County Boundary

Wind Cave National Park, South Dakota - Rozol use is prohibited within this area.

Custer State Park, South Dakota - Rozol use is prohibited within this area.

Figure 11. Logan County, KS

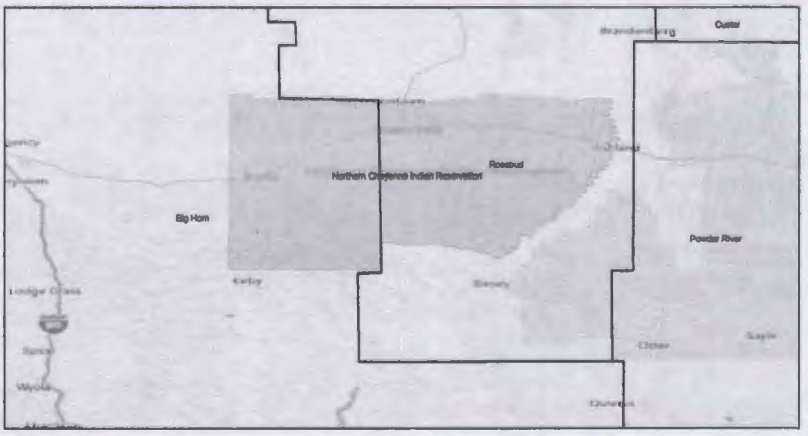


Legend

County Boundary

Logan County, Kansas ferret areas - Rozol use is prohibited within these areas.

Figure 12. Northern Cheyenne Indian Reservation, MT



Legend

County Boundary

Montana Indian Reservations (Northern Cheyenne Indian Reservation) - Rozol use is prohibited on Tribal lands within the Northern Cheyenne Indian Reservation.

Figure 13. Vermejo Park Ranch, NM

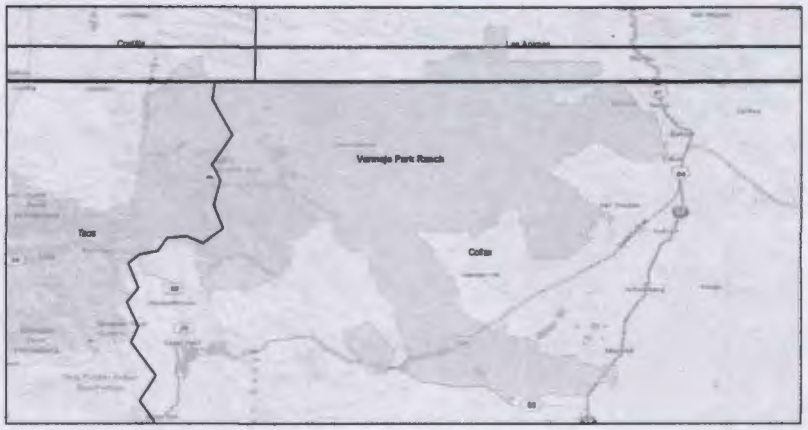


Figure 14: 2011 10 20 MISC grizzly bear time restriction map.pdf

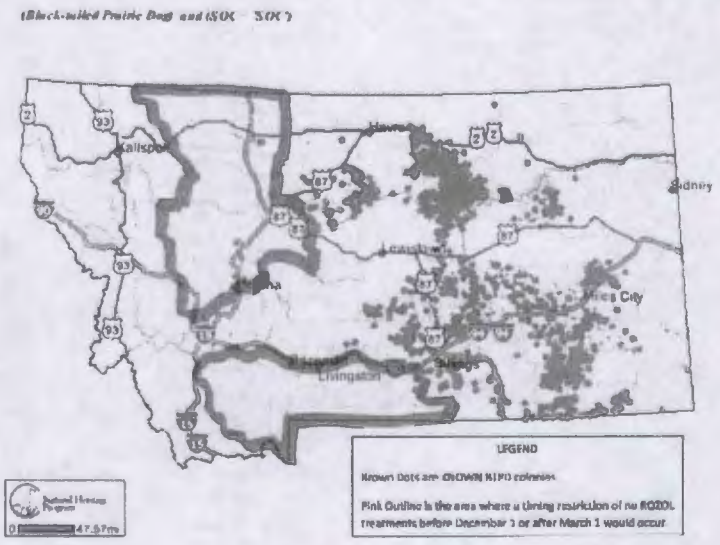
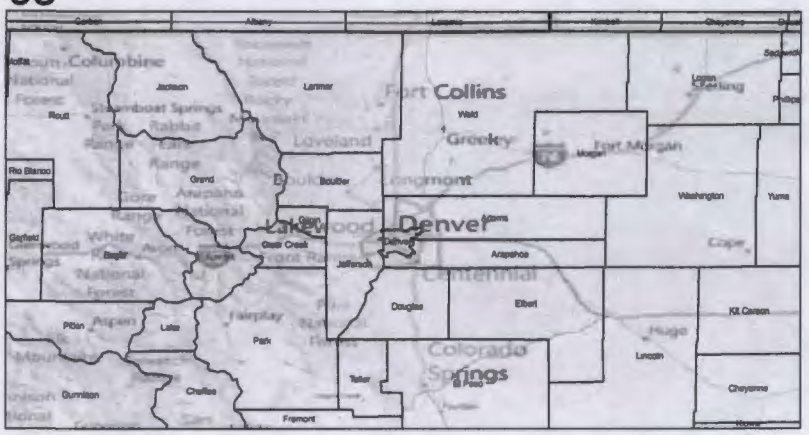


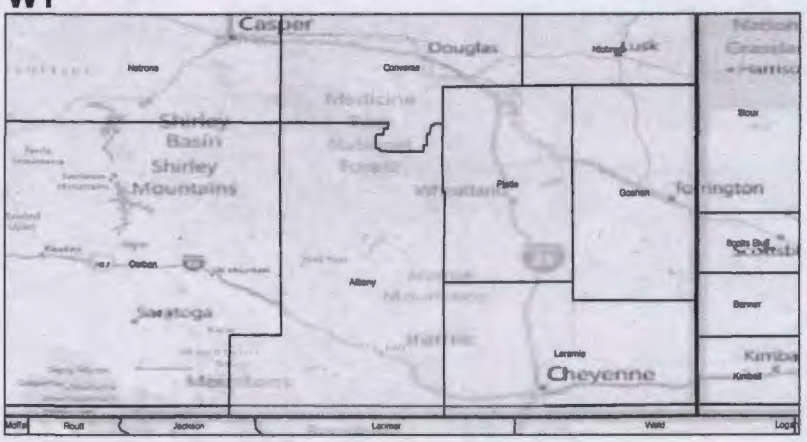
Figure 15. Preble's Meadow Jumping Mouse (PMJM), CO



Legend

- County Boundary
- PMJM Colorado - Rozol use is limited to the period November 1 - March 15.
- PMJM Wyoming - Rozol use is limited to the period November 1 - March 15.

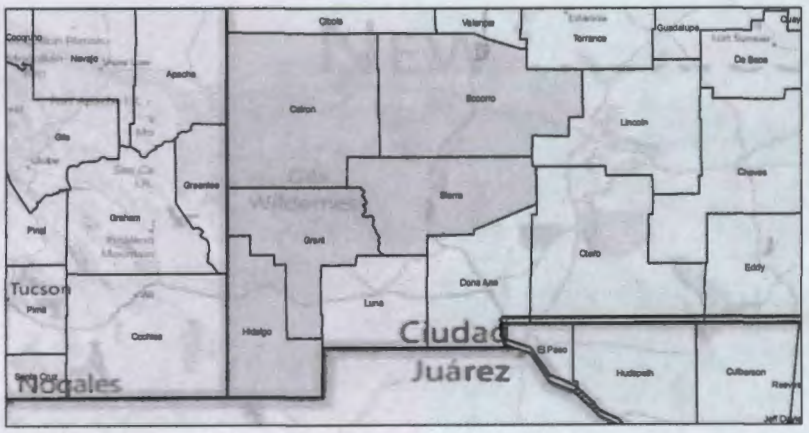
Figure 16. Preble's Meadow Jumping Mouse (PMJM), WY



Legend

- County Boundary
- PMJM Wyoming - Rozol use is limited to the period November 1 - March 15.
- PMJM Colorado - Rozol use is limited to the period November 1 - March 15

Figure 17. Five County Rozol Exclusion Area in NM



Dated: November 22, 2011

Respectfully Submitted,

IGNACIA S. MORENO
Assistant Attorney General
SETH M. BARSKY
Section Chief
S. JAY GOVINDAN
Assistant Section Chief

/s/ Kristen Byrnes Floom
KRISTEN BYRNES FLOOM, Trial Attorney
(D.C. Bar No. 469615)
Wildlife & Marine Resources Section
Ben Franklin Station
P.O. Box 7369
Washington, DC 20044-7369
Phone: (202) 305-0340
Fax: (202) 305-0275
Email: kristen.floom@usdoj.gov

Of counsel:
DAVID N. BEROL
Office of General Counsel
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Attorneys for Federal Defendants

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLUMBIA

DEFENDERS OF WILDLIFE, et al., Plaintiffs, v. LISA P. JACKSON, Administrator of the United States Environmental Protection Agency, et al., Defendants, LIPHA TECH, INC., Defendant-Intervenor.	No. 1:09-cv-01814-ESH (consolidated with No. 1:10-cv-01063-ESH)

DRAFT DECLARATION OF GARY FRAZER

I, Gary Frazer, declare as follows:

1. I am the Assistant Director for Endangered Species for the United States Fish and Wildlife Service (Service), an agency with the United States Department of the Interior (Department), located in Washington, District of Columbia. In my capacity as Assistant Director, I am responsible to the Director of the Fish and Wildlife Service. I work directly with the Department's Assistant Secretary for Fish and Wildlife and Parks as well as the Secretary of the Interior.

2. The Service has the delegated authority for the administration of the Endangered Species Act (ESA), 16 U.S.C. 1531 et seq., including consultations under section 7 of the ESA. Under

section 7, formal consultation between a federal agency and the Service is required if a proposed action is likely to adversely affect a listed species or its critical habitat. Consultation concludes when the Service issues a biological opinion, which describes how the agency action affects a listed species or its critical habitat, makes a conclusion about whether the action is likely to jeopardize listed species or adversely modify or destroy critical habitat, and, if appropriate, includes an incidental take statement. In my capacity as Assistant Director, my duties include working with my staff to coordinate certain consultations under section 7 at the national level. In particular, my staff and I are frequently involved in consultations that are of national importance or involve consultations involving more than one region.

3. As part of my duties as Assistant Director, I am familiar with the consultation involving the rodenticide Rozol. Rozol is proposed for use in states covered by two of the Service's regional offices - Region 2 (located in Albuquerque, New Mexico) and Region 6 (located in Denver, Colorado). These two regions are coordinating the consultation.

4. The Service received the Environmental Protection Agency's (EPA) effects analysis and request for consultation on September 30, 2010. EPA's analysis concluded that registration of Rozol may affect, and was likely to adversely affect, 21 listed species. To date, the Regions have begun the consultation process by establishing points of contacts for each species, identifying a lead Region and Field Office personnel, and working with EPA and the applicant, Liphatech, Inc., to develop conservation measures to avoid and lessen impacts to ESA listed species from Rozol use on black-tailed prairie dogs. Species leads in both regions are providing analysis and input to Region 6, which is responsible for collating the information and writing the biological opinion.

5. The consultation involves reviewing the potential effects of the proposed action on approximately 21 species and seven critical habitat designations (not all of which may be adversely affected by the action). This process requires review of EPA's effects analysis, which describes the action area, the status of the species and any relevant critical habitat, and the effects of the action (including direct, indirect, and cumulative effects of the action, as well as the effects from any interrelated or interdependent actions) on any listed species or critical habitat. After this review, and using the best available scientific and commercial data, the Service will determine whether EPA's registration of Rozol is likely to jeopardize the continued existence of any listed species or adversely modify or destroy any critical habitat.

6. If the action is not likely to jeopardize any listed species but take is expected, we issue an Incidental Take Statement (ITS). We are required to include in the ITS any reasonable and prudent measures (and terms and conditions to implement those measures) that will minimize the impact of the effects of the action under consultation. Under section 7 regulations, these measures can only result in minor changes to the proposed action.

7. If we determine that the action is likely to jeopardize any listed species or destroy or adversely modify critical habitat, we are required under the ESA to attempt to find a reasonable and prudent alternative to the action that would allow the action to go forward but not jeopardize listed species or adversely modify or destroy critical habitat.

8. An important component of section 7 consultation involves discussions with the applicant to avoid and minimize impacts of the proposed project or action to listed species. These negotiations provide an opportunity to try to develop measures to avoid jeopardy, reduce adverse effects, and minimize incidental take of listed species.

9. We have had two conference calls with EPA and the Rozol applicant, Liphatech, Inc., where we detailed impacts to listed species from the proposed use of Rozol and identified key areas where limitations or prohibitions on Rozol use would materially reduce the impacts to listed species. Liphatech is amenable to geographic and/or timing restrictions on the use of Rozol to avoid or minimize impacts to listed species. Further, Liphatech has also expressed a willingness to request a label amendment such that use of Rozol would be prohibited in all black-footed ferret reintroduction sites (currently 12) within the range of black-tailed prairie dogs where Rozol is proposed for black-tailed prairie dog control. The prohibition on Rozol use in black-footed ferret reintroductions sites will be identified in EPA county bulletins with an appropriate level of specificity. Black-footed ferrets are an endangered species that are an obligate predator of black-tailed prairie dogs and live in their burrow systems within the prairie dog colony. Maps of all ferret reintroductions have been provided to EPA. To avoid impacting ferret reintroduction areas, the Service is currently negotiating with EPA and Liphatech where Rozol use would be prohibited. The ferret reintroduction areas where Rozol would be prohibited are pivotal to the jeopardy analysis in the biological opinion because two-thirds of all ferret reintroductions and approximately 60 percent of all known ferrets are located in black-tailed prairie dog habitat. Absent measures to exclude Rozol use at these ferret sites, ferret recovery could be compromised.

10. We previously believed that a draft biological opinion could be produced by December 10, 2011. The negotiations with Liphatech and EPA for developing exclusion zones and timing restrictions on Rozol use areas are producing significant benefits for listed species (avoiding impacts and reducing take), but those negotiations have made the earlier timeframe unrealistic. FWS requested an extension of the original December 10, 2011 due date for the draft biological

opinion, and EPA suggested a new deadline of January 16, 2012. This date would provide additional time to complete the negotiations with Liphatech and the draft biological opinion without conflicting with EPA's timeframe to get county bulletins in place approximately six months before the beginning of the next Rozol use season starting October 1, 2012.

11. The Service will transmit the draft biological opinion to EPA by January 16, 2012. It will then be reviewed by EPA and the applicant, in keeping with the counterpart regulations governing actions taken under FIFRA (50 C.F.R. § 402.46(c)). Under 50 CFR 402.46(c)(3), the Service has the authority to issue its final biological opinion within 45 days of transmitting the draft biological opinion to EPA unless the Service and EPA mutually agree to an extension of the due date for the final biological opinion. However, we understand that EPA and the applicant expect to provide comments on the draft biological opinion within 45 days after receipt of the draft biological opinion. In that event, barring unforeseen circumstances, the Service anticipates issuing a final biological opinion within 30 days of receiving comments from EPA and the applicant.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge. Executed this 22nd of November, 2011, at Washington, D.C.

GARY FRAZER

LIPHATECH

3600 WEST ELM STREET
MILWAUKEE, WI 53209
Tel: 414/351 1476 800/351 1476
Fax: 414/247 8166

484102-00

Document Processing Desk
EPA Office of Pesticide Programs (7504P)
One Potomac Yard, Room S4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: John Hebert, Insecticide/Rodenticide Branch

March 1, 2011

Re: Additional information concerning
"Rozol Prairie Dog Bait" EPA Reg. No. 7173-286

Dear Mr. Hebert,

The enclosed study is submitted in support of our product "Rozol Prairie Dog Bait," EPA Reg. No. 7173-286. The study was designed to gather factual data concerning the availability of "intoxicated" prairie dogs on the surface of the ground following application of the Rozol bait product. The study found no intoxicated prairie dogs (and no prairie dog carcasses) on the ground surface for the three weeks following a commercial bait application at that specific site, at that specific time.

This information is relevant to the EPA's consultation with US Fish and Wildlife Service concerning the registration of Rozol Prairie Dog Bait, pursuant to EPA's "Chlorophacinone Effects Determination" dated September 29, 2010 and published on EPA's website. As such, we request that this study also be forwarded by EPA to the US FWS, for use in their review process.

Thank you for your attention to this matter. Please contact me directly if there is any problem or question concerning this submission.

Sincerely,

Thomas Schmit
Manager of Regulatory Affairs

cc: Ms. Melissa Grable, EPA Environmental Fate and Effects Division

LIPHATECH

3600 WEST ELM STREET
MILWAUKEE, WI 53209
Tel: 414/351 1476 800/351 1476
Fax: 414/247 8166

TRANSMITTAL DOCUMENT

Name and address of Submitter:

Liphatech, Inc., 3600 W. Elm Street, Milwaukee, WI 53209

Regulatory Action in Support of Which this Package is Submitted:

Rozol Prairie Dog Bait, EPA Reg. No. 7173- 286

Transmittal Date: **March 1, 2011**

List of Submitted Studies:

Volume 1: Administrative materials
- Cover letter dated March 1, 2011

48410201 **Volume 2:** **Rozol Prairie Dog Bait: Availability of "Intoxicated" Prairie Dogs**
(Guideline number none) (LTI Number 10005)

Company Official: Thomas Schmit

Thomas Schmit, Manager of Regulatory Affairs
Liphatech, Inc., 3600 W. Elm Street, Milwaukee, WI 53209
phone (414) 410-7230
fax (414) 247-8172
e-mail schmitt@liphatech.com

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 10, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

THOMAS SCHMIT
LIPHATECH, INC.
3600 W. ELM STREET
MILWAUKEE, WI 53209

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 04-MAR-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: 2/1/2011
PC code: 067707
DP barcode: 385211

SUBJECT: **Response to rebuttal of "Chlorophacinone (067707): Secondary review of 'Determination of Chlorophacinone Residues in Prairie Dog Whole Body and Liver Tissues'".**

FROM: **Andrew Shelby, Physical Scientist**
Environmental Fate and Effects Division/ERB 6 (7507P)

THRU: For **Christine Hartless, Wildlife Biologist, ERB 2** 2/1/11
Brian Anderson, Branch Chief, ERB 2
Environmental Fate and Effects Division (7507P)

TO: **Dan Peacock, Risk Manager Reviewer**
Registration Division (7507P)

The Environmental Fate and Effects Division (EFED) had previously received a field efficacy/hazard study (MRID 47333602) and a carcass residue study (MRID 47333603) utilizing carcasses from the aforementioned study. MRID 47333602 was reviewed by EFED and considered to be invalid. MRID 47333603 was reviewed by EFED and considered to be supplemental but submission of carcass handling methods was requested. This submission, DP barcode 385211 and MRID 48294401, addresses the carcass handling methods. After reviewing this submission, EFED considers all three studies (MRIDs 47333602, 47333603 and 48294401) to be supplemental because, when considered together, they provide relevant information regarding chlorophacinone residues in black-tailed prairie dogs.

EFED has reviewed the rebuttal to the review of the "Determination of Chlorophacinone Residues in Prairie Dog Whole Body and Liver Tissues" submitted under MRID 48294401. The study in question is MRID 47333603 and was initially reviewed under DP Barcode 350010. As requested, the study director, Charles Lee of Kansas State University, has submitted a letter detailing the carcass handling methods for the method validation set of animals and the field study set of animals. Study reclassifications as a result of this re-review follow:

Environmental fate data requirements for chlorophacinone		
MRID	**Study Classification[1]**	**Remarks**
47333602	Supplemental (non-guideline)	Supplemental only for hazard component; only indicates that exposure occurs
47333603 and 48294401	Supplemental (non-guideline)	The study and accompanying letter describing carcass handling are to be considered together
[1]**OPPIN Classifications:** **Acceptable/Guideline; Acceptable/Non-Guideline; Cited; Confirmatory; Decision Deferred; Extraneous submission; In Review; No Decision; Partially Acceptable; Supplemental: Unacceptable/Guideline; Unacceptable/Non-Guideline; Upgradeable.**		

In any of the submitted documentation, the only characterization of animals collected for method validation is that they were "collected in an intense survey effort from a wide geographic area where it was known Rozol had been applied." Assuming that applicators applied Rozol Prairie Dog Bait according to label instructions, no distinction can be made between animals in the method validation group and animals in the field study group. The only distinction between methods in the field study and label instructions is the frequency of carcass collections. Carcass collection for the field study group was more frequent than what is required on the label (EPA Reg. No. 7173-286). However, it is reasonable to assume that carcass collection for the method validation group may have been more frequent than the label requires considering it was a "collection effort".

When presenting two comparable datasets with a significant difference between them, it is advisable to fully characterize similarities and differences between the datasets. These distinctions include fully characterizing methods in practice and the circumstances under which baiting was performed. When this information is unavailable, conservative assumptions will be made. Though the performing laboratory (USDA National Wildlife Research Center) only required the carcasses for developing the analytical techniques, the tracking of methods prior to delivery of the carcasses is under the study director's discretion. If there was any possibility that the results of the method validation would be presented in the study report, it would have been reasonable to include the same information for the method validation set as were included for the field study set.

Carcass handling methods, as described, are acceptable. There is no longer reason to suspect intermittent thawing or poor handling of carcasses occurred and no more information regarding carcass handling methods is required. The analysis of residues is scientifically sound, however, it will continue to be categorized as **supplemental** because the study does not fulfill a guideline requirement under 40 CFR 158. However, the carcasses provided for residue analysis were not collected in such a way that peak residue concentrations could be determined. Determination of peak residue concentrations would require the testing of animals before they succumb to chlorophacinone poisoning or immediately after they expire. Carcass collection every other day does not allow for this determination. Though the study was not designed to determine the sources of variability in carcass residue concentrations, the intent of the study design was to at least capture the variability. Though incomplete methods from the method validation set preclude direct comparison, residue concentrations differ significantly which indicates that the range of variability in residue concentrations may not have been captured in the field study set. Other explanations for the differences between sets can be made but none can be proven without more complete characterization of the methods.

Residue concentration data from MRID 47333603 can be used to generally characterize residue concentrations in black-tailed prairie dogs but cannot be relied upon to quantitatively represent high-end

exposure from black-tailed pra[redacted]g exposure for two reasons: (1) car[redacted]ollection did not occur with enough frequency to assure detections of high-end exposure, and (2) the range of residue concentration variability was not necessarily captured. These deficiencies reflect upon the utility of the data derived from the residue analysis but does not call into question the quality of the residue analysis.

The associated field hazard study, MRID 47333602, indicates that poisoned carcasses are available on the ground surface following baiting and that non-target animals (*i.e.* the cottontail rabbit) can be lethally exposed to the bait. Because the study provides this information and provided carcasses for residue analysis, it will be categorized as **supplemental**. The field hazard study *does not* indicate the following: to what extent carcasses are available on the surface, to what extent carcass collection mitigates exposure on the surface, or carcass collection efficiency. Because available carcasses and duration of exposure cannot be quantified from this study, conservative assumptions will be made when assessing risk.

[redacted]ED STATES ENVIRONMENTAL PROT[redacted]ON AGENCY
WASHINGTON, D.C. 20460

November 16, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

LIPHATECH, INC.
3600 W. ELM STREET
MILWAUKEE, WI 53209

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 15-NOV-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

LIPHATECH

482944-00

3600 WEST ELM STREET
MILWAUKEE, WI 53209
Tel: 414/351 1476 800/351 1476
Fax: 414/247 8166

TRANSMITTAL DOCUMENT

Name and address of Submitter:

Liphatech, Inc., 3600 W. Elm Street, Milwaukee, WI 53209

Regulatory Action in Support of Which this Package is Submitted:

Rozol Prairie Dog Bait,
EPA Reg. No. 7173-286

Transmittal Date: **November 12, 2010**

List of Submitted Studies:

48294401 Volume 1: Rebuttal to "Chlorophacinone (067707): Secondary exposure review of "Determination of Chlorophacinone Residues in Prairie Dog Whole Body and Liver Tissues" dated September 3, 2009, by Andrew Shelby

Company Official: Thomas Schmit

Thomas Schmit
Manager of Regulatory Affairs
Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209
414-410-7230 phone
414-247-8172 fax
schmitt@liphatech.com

LIPHATECH

3600 WEST ELM STREET
MILWAUKEE, WI 53209
Tel: 414/351 1476 800/351 1476
Fax: 414/247 8166

Document Processing Desk
EPA Office of Pesticide Programs (7504P)
One Potomac Yard, Room S4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Mr. John Hebert, Insecticide/Rodenticide Branch

Via Federal Express

12 November, 2010

Re: Rebuttal to
"Chlorophacinone (067707): Secondary exposure review of "Determination of Chlorophacinone Residues in Prairie Dog Whole Body and Liver Tissues" dated September 3, 2009, by Andrew Shelby (copy enclosed)

Dear Mr. Hebert,

This study on prairie dog carcass residues (MRID47333603) was performed by the USDA National Wildlife Research Center laboratory (NWRC), but the carcasses that were analyzed were collected by Charles Lee. As you may recall, Charles Lee conducted the actual field efficacy study on prairie dogs and wrote that study report (MRID 47333602). Mr. Lee is an experienced wildlife scientist employed by the Kansas State University as an Extension Specialist, with many years of experience with wildlife studies. He has a thorough understanding of field study techniques and procedures, and has published many papers in scientific journals (See Lee's *curriculum vitae* attached).

In Mr. Shelby's review of the NWRC carcass residue study, he alleges that "... carcass handling methods were not described and intermittent thawing and/or poor landling practices prior to residue determination do not allow for a conservative determination of chlorophacinone concentrations." He concludes that "This study is classified as "supplemetal". Though the residue analysis presented in Table 1 may be accurate, the suspected mishandling of carcasses in the other analysis calls into question the handling methods for both analysis." Apparently, the only basis for suspecting mishandling is that the residue levels of one group of carcasses differs from the residue levels of the second group of carcasses.

Following our receipt of this review, Charles Lee submitted a rebuttal to Mr. Shelby's allegations of mishandling, in a letter dated November 30, 2009 and addressed to you, specifically requesting that the letter be made part of the data package to be re-reviewed. IN his letter, Lee reports that he personally collected the carcass specimens in question, and describes the proper handling used to submit these carcasses to the NWRC laboratory. All carcasses that he collected were immediately frozen, kept frozen until submission to NWRC, and shipped to the NWRC lab in suitable packaging to maintain them in a frozen state. There clearly was no "intermittent thawing and/or poor landling practices" of the carcasses.

As pointed out in Lee's letter, the carcasses shown in Table 1 were collected and sent at the request of the NWRC laboratory, for the sole purpose of development / validation of the analytical method. They were collected randomly, from sites where Rozol Prairie Dog Bait has been previously applied by the manager of that land. Lee had no information about the Rozol application other than the one fact there had been an application made at that site. At the same time, Lee collected carcasses from untreated sites, by shooting the prairie dogs. Again, this was done at the request of the laboratory for development / validation of the analytical method.

Due to the lack of context for these initial carcass analyses (as reported on Table 1) perhaps they should not have been included in the study report. As the sponsor, we could have directed the NWRC to omit them from their report. We did not do so, as we felt it appropriate to submit as much data as possible concerning carcass residues – even when the specific details of the application are not known. At that time, we did not anticipate that a reviewer would question the integrity of these analyses simply because of differing results between the groups.

We now recognize that this information has not been made part of the study record, and that the residue study has not been re-reviewed. This conclusion is based on the "*Nation-wide Effects Determination for Chlorophacinone Relative to the Use of Rozol Prairie Dog Bait*" dated 9/29/2010 and currently posted on EPA's website. This document, co-authored by the same Andrew Shelby, continues to maintain that this residue study is "supplemental" due to carcass handling problems (page 66 of the cited document).

Therefore, we are re-submitting Charles Lee's letter through the document processing desk, with a transmittal document, in order to have an MRID number assigned to it. We respectfully insist that this letter and Dr. Lee's information be attached to the original study (MRID 47333603).

Thank you for your attention to this matter. Please contact me directly if there is any problem or question concerning this submission.

Sincerely,

Thomas Schmit
Manager of Regulatory Affairs

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

October 18, 2010
PC Code: 067707
DP Barcode: 351036
Decision #: 388661
Product #:7171-242

SUBJECT: Chlorophacinone (067707): Non-target exposure review of "Assessment of the Potential Impact of Chlorophacinone on Burying Beetles"

FROM: Melissa Grable, Biologist
Environmental Fate and Effects Division (MC 7507P)

SECONDARY REVIEW: Donna Randall, Senior Effects Scientist
Environmental Fate and Effects Division/ERB2

THRU: Jean Holmes, Acting Branch Chief
Environmental Fate and Effects Division/ERB2 (MC 7507P)

TO: Dan Peacock
Registration Division/IRB (MC 7505P)

Attached is EFED's review of the two phase study: "Assessment of the Potential Impact of Chlorophacinone on Burying Beetles". The first phase was titled the: "Investigation of any acute or chronic effects of chlorophacinone upon *Nicrophorus* larvae developing in dosed carcasses and the subsequent generation of adults produced from those carcasses." The second phase was titled the: "Investigation of any direct acute or chronic effects of chlorophacinone upon *Nicrophorus* adults and the subsequent ability of those adults to brood and produce normal progeny." In the first phase of the study, significantly fewer beetles emerged from the chlorophacinone-dosed rat carcasses than the control/undosed carcasses. The lack of effects on beetle production when adults are exposed to chlorophacinone but their larvae are not and reduced number of emerged beetles when larvae are exposed to chlorophacinone but adults are not until brooding of young indicate that larvae are more sensitive to chlorophacinone than adults. Other than larval survival, no effects on adult survival, fecundity, larval growth or male-female sex ratio were detected at environmental levels. This study is not a guideline study, and no protocols

were submitted to the Agency for review and comment prior to the conduct of the study. However, a protocol was submitted with the final report. For both phases of the study the use of the term "acute" is misleading as the exposure duration to chlorophacinone was not acute in either phase neither were they full life cycle tests, but are instead subchronic tests with exposure occurring at critical life stages.

EFED concludes that the study provides useful information regarding effects of chlorophacinone on non-target insects. However, the study lacks critical test protocol information and raw data were not provided. Summarized results for replicates were provided in Excel spreadsheets but without raw data sheets these could not be independently verified. An independent statistical analysis conducted using these results found study conclusions that differed in part from those in the study report. Furthermore, the study, which was conducted at a university laboratory, was not conducted under 40 CFR Part 160 Good Laboratory Practices (GLP). At a minimum, basic study reporting elements outlined under GLP were not provided in the protocol or study report. The study is classified as "Supplemental/Non-Guideline". It should be noted that there is no OCSPP guideline for this study and no standard test methodology (*e.g.*, ASTM) was followed.

Please contact Melissa Grable at 703-308-3953, Donna Randall at 703-605-1298, or Andrew Shelby at 703-347-0119 if you have any questions.

Environmental toxicity data requirements for chlorophacinone

MRID	Study Classification[1]	Remarks
473830-01	Supplemental/Non-Guideline	Phase I study: provides semi-quantitative results Phase II study: provides semi-quantitative results

[1]OPPIN Classifications:
Acceptable/Guideline; Acceptable/Non-Guideline; Cited; Confirmatory; Decision Deferred; Extraneous submission; In Review; No Decision; Partially Acceptable; Supplemental: Unacceptable/Guideline; Unacceptable/Non-Guideline; Upgradeable.

Data Evaluation Repo[redacted]he toxicity effects of chlorophaci[redacted]TEP on a species of burying beetle, *Nicrophorus orbicollis*

EPA MRID Number 473830-01

Data Requirement: Non-Guideline – 40 CFR § 158.590 Special Nontarget Insect Testing

Chemical: Chlorophacinone

PC Code No.: 067707

Test material:

Phase I: Chlorophacinone bait — Purity: 50 mg/kg
End use product not specified; certificate of analysis states "chlorophacinone pellets"

Phase II: Study report states chlorophacinone concentrate — Purity (%): 2
However, the Protocol states diphacinone-form unspecified — Purity: Not specified

Primary Reviewer: Melissa Grable
Biologist, EFED
Signature: Melissa M. Grable 10/18/10
Date: 10/18/2010

Secondary Reviewer(s): Donna M. Randall
Senior Effects Scientist, EFED ERB II
Signature: Donna M Randall 10/18/10
Date: 10/18/2010

CITATION: Horn, David J. and George Keeney, 2007, "Assessment of the Potential Impact of Chlorophacinone on Burying Beetles". Performing laboratory: Ohio State University, Department of Entomology, 318 West 12th Avenue, Columbus, OH 43210-1242. Project Identification Number: None. Sponsored by Liphatech, Inc., 3600 W. Elm Street, Milwaukee, WI 53209.

EXECUTIVE SUMMARY:

The effect of chlorophacinone on the survival, reproductive success and larval growth of a species of burying beetle, *Nicrophorus orbicollis*, was assessed in a two phased study. In the first phase of the study each of 20 mature male-female pairs of field-collected *N. orbicollis* beetles was offered a chlorophacinone-dosed rat carcass. Each of an additional 20 mature male-female beetle pairs of field-collected *N. orbicollis* was offered an undosed rat carcass as a control. Upon emergence of offspring (approximately one month later), the total number of young produced per brood was counted, sexed, and weighed. The chlorophacinone-dosed carcasses were a group of 20 rats fed exclusively 50 mg a.i./kg chlorophacinone bait for a period of 5 to 10 days until death. A group of 20 undosed rats which were fed a standard laboratory rodent diet were used as controls. No analysis was made of chlorophacinone residue levels in rat carcasses. The number of emerged beetles, the male-female ratio, and individual beetle and total brood weight of treatment and control broods were compared using nonpaired t-tests. Significantly fewer beetles emerged from the chlorophacinone-dosed rat carcasses than the control/undosed carcasses. Total biomass, which is not independent of brood size, was also

significantly reduced on chlorophacinone-dosed carcasses; however, growth of individuals (total biomass adjusted for brood size) was not significantly different. Additionally, no effect was observed on the male-female ratio.

The second phase of the study was divided into two parts. The first part was a 28 day feeding trial where 64 (36 females/28 males) adult *N. orbicollis* beetles were fed chlorophacinone-dosed (3.0 ppm chlorophacinone) ground beef and another 64 (36 females/28 males) beetles were fed undosed ground beef. In the second part of this study phase, 10 surviving male/female pairs from the chlorophacinone exposed adults in part 1 and 10 surviving male/female pairs from the control adults in part 1 were each provided an undosed quail carcass. Upon emergence of offspring (approximately one month later), the total number of young produced per brood were counted, sexed, and weighed. Number of emerged beetles, the male-female ratio, and individual beetle and total brood weight of treatment and control broods were compared using nonpaired t-tests. Survival of adults fed chlorophacinone at 3.0 ppm was not significantly reduced and there was no significant decrease in offspring production and growth as determined by number of emerged beetles, total biomass, individual beetle weight, and male-female ratio.

The lack of effects on beetle production when adults are exposed to chlorophacinone but their larvae are not and reduced number of emerged beetles when larvae are exposed to chlorophacinone but adults are not until brooding of young indicate that larvae are more sensitive to chlorophacinone than adults. Other than larval survival, no effects on adult survival, fecundity, larval growth or male-female sex ratio were detected at environmental levels.

This study is classified as Supplemental/Non-guideline. It should be noted that there is no guideline for this study. The study provides useful information regarding effects of chlorophacinone on nontarget insects but critical information is lacking on protocols, there is a lack of analytical data on residue levels on chlorophacinone fed rat carcasses, and a lack of raw observation data to allow validation of results.

I. MATERIALS AND METHODS:

GUIDELINE FOLLOWED: Non-guideline study. A standard protocol for production of American burying beetles used by the laboratory was cited as being used for production of the congeneric species tested within this study, but this protocol was not provided in the study report nor alternatively was a citation provided for location of the protocol within the open literature. No other standard test methodology (*e.g.*, ASTM) or source for the study design and conduct was cited.

COMPLIANCE: Report contains a signed and dated statement of no confidentiality and a signed statement that the study was not conducted under 40 CFR 160 GLP.

A. MATERIALS:

1. **Test Material:** Phase I: Chlorophacinone bait — **Purity (%) a.i.**: 0.00561
   Phase II: Chlorophacinone concentrate — **Purity (%) a.i.**: 2.05

Data Evaluation Repo[redacted] the toxicity effects of chlorophaci[redacted] TEP on a species of burying beetle, *Nicrophorus orbicollis*

EPA MRID Number 473830-01

Description: Phase I: Chlorophacinone pellets
Phase II: not reported

Lot No./Batch No.: Phase I: 19406
Phase II: 058061

Stability of Compound Under Test Conditions: Phase I: No information was provided on the stability of the compound under the test conditions.

Phase II: No information was provided on how many batches of ground beef were prepared, how frequently adults were fed, storage method or duration of storage of dosed ground beef until being fed to beetles, and no analytical analysis was conducted to confirm the concentration or stability of the active ingredient in the ground beef.

Storage conditions of Test chemicals: Certificates of analysis on the test substances were provided which document their purity at the time of analysis. However, a significant amount of time likely passed between when they were used in this study and these analyses, but no information was provided in the study report to document how these test materials were stored to ensure the stability and integrity of this purity prior to use. The certificate of analysis for the test material used in Phase I was over a year old by the time the certificate of analysis for the test material used in Phase II was conducted. It is unclear when the study was performed and therefore the test materials for Phase I and Phase II could have been stored for several months before the study was conducted.

2. Test Organism:

Species: burying beetle, *Nicrophorus orbicollis* which is a species related to the American burying beetle (*Nicrophorus americanus*).

Age at test initiation: Phase I: field collected adults were used. All field collected beetles were held in captivity for a period of three weeks prior to their use in this trial to ensure minimum reproductive maturity. However, the specific age and maturity of ovaries and any prior mating history is unknown. Variability among beetles in these factors may result in variability in reproductive success (Creighton 2005).

Phase II: Adults were used, but no information was provided regarding their specific adult age, closeness in age, or reproductive history.

Length: No information was provided on the range in lengths or mean length of the adults used in either phase of the study. Studies with burying beetles species

have shown that length of adults is significantly related to reproductive success in terms of number of eggs oviposited and number of emerged beetles from a brood (Creighton 2005).

Source: Phase I: adults were identified as being collected from the field. It appears from the draft budget section of the study that the beetles were collected from the Waterloo Wildlife Area. However, the specific location or locations within the Waterloo Wildlife Area were not provided nor did the study report identify if this site was where the beetles were actually collected from or if, an alternative site or sites were used. Differences in density of burying beetles (*i.e.*, competition pressure) between field collection sites has been significantly related to the number of larvae produced and number of emerged beetles (Creighton 2005).

Phase II: Source of adults used in this phase was not specifically stated. This can have a major impact on study results as discussed in the preceding paragraph.

B. STUDY DESIGN:

1. Experimental Conditions:

a. Soil: Source and characteristics of soil or burial media were not described. The study did not state if the same media was used for both phases of the study or all replicates.

b. Acclimation: During the first phase of the study, field collected burying beetles, *Nicrophorus orbicollis*, were used. Field collected beetles were held in captivity for three weeks prior to their use in the trial to ensure minimum reproductive maturity. During the second phase of the study it was stated that adult beetles were used but it did not state how adult status was determined.

c. Duration: Experimental study dates for each phase were not provided, nor were specific times provided.

Phase I: Approximately one month. The study stated that the results were compiled upon emergence of offspring (approximately one month).

Phase II: The first part of this phase of the study consisted of a 28 day feeding study. The second part of this phase of the study also stated that the results were compiled upon emergence of offspring (approximately one month).

d. Health: The health of the test organisms was not mentioned in the study.

e: Test Container: The draft budget section of the study stated that rearing buckets and plastic holding containers were purchased but the dimensions of the test containers,

construction materials of the containers, and depth of soil in the containers were not specified in the study.

f. No. of replicates: Phase I: 20 replicates each for treatment and control.

Phase II: In the first part of the second phase of the study, there were 64 replicates each for the treatment and control. In the second part of the second phase of the study, there were 10 replicates each for the treatment and control.

g. Test conditions (temperature, light, moisture, etc.): No information was provided in the study describing the air and soil temperature, light conditions, humidity or soil moisture.

h. Observations: The study stated that treatment beetles were closely observed for aberrant behavior during burial and brooding. However, no observation results or description were provided in the study.

i. Were raw data included? No, raw data sheets were not provided. Summarized results for replicates were provided in Excel spreadsheets but without raw data sheets these could not be independently verified.

II. REPORTED RESULTS AND STATISTICS:

A summary of the measured and calculated response variables from Phase I, Phase II-Part 1, and Phase II-Part 2 are provided in Tables 1, 2, and 3 respectively. The Excel spreadsheet with replicate responses had statistical results for the Phase I conducted using a paired t-test and the assumption of equal variance. The study design is an unpaired design not paired, and the assumption of equal variance is not appropriate for several of the variables, therefore the statistical findings in Table 1 are based on the reviewer's reanalysis conducted under verification of statistical results. Additionally, a transformation of data was conducted (Log [No. of beetles] + 1) rather than (Log [No. of beetles +1]), in Phase I and Phase II-Part 2 and was not included in this review, as this analysis was not needed.

Based on the change in the statistical methods for Phase I, the findings differed for some measures as compared to the report. The following discussion of the findings for Phase I are based on the reviewer's reanalysis of the results. Significantly fewer beetles emerged from the chlorophacinone rat carcasses than the control carcasses. Total biomass, which is not independent of brood size, was also significantly reduced on chlorophacinone-dosed carcasses; however, growth of individuals as represented by average beetle weight (total biomass adjusted for brood size) was not significantly different. Additionally, no effect was observed on the male-female ratio (absolute male and female numbers were not evaluated because the results are not expected to be independent from the impact to reduced number of emerged beetles).

A statistical analysis was not conducted for Phase II-Part 1 as adult beetle mortality in the chlorophacinone treatment was equal to or lower than in control beetles overall, and for females.

Based on these results chlorophacinone residues at levels of 3.0 ppm and lower are not expected to affect adult survival.

Table 1: Means of measured and calculated response variables from Phase I

Measured or Calculated Response Measure	Control Mean (SD)	Treatment Mean (SD)
Carcass weight (g)	**102.80 a (5.55)**	**89.65 b (7.32)**
No. of beetles produced	**22.50 a (12.33)**	**12.75 b (9.56)**
No. beetles/gram carcass wt.	**0.225 a (0.114)**	**0.158 b (0.104)**
Average beetle weight	0.40 a (0.049)	0.42 a (0.057)
Estimated total brood weight (g)	**9.19 a (5.16)**	**5.24 b (3.79)**
Brood weight (g)/carcass weight (g)	**0.09 a (0.048)**	**0.07 b (0.041)**
Male-female ratio/brood	1.01 a (0.49)	1.39 a (0.99)

Numbers followed by the same letter are not significantly different, results shown are based on reviewer's statistical results using nonpaired t-tests assuming unequal variance (Excel spreadsheet provided by testing facility had paired t-test results with assumption of equal variance)

Table 2: Phase II-Part 1 Adult mortality during 28-day feeding trial

Mortality	Control	Treatment
Males and females combined	12.5%	4.7%
Males	3.1%	3.1%
Females	9.4%	1.6%

No statistics were performed as mortality in chlorophacinone treatment was equal to or lower than in control beetles.

Table 3: Means of measured and calculated response variables from Phase II-Part 2

Measured or Calculated Response Measure	Control Mean	Treatment Mean
Carcass weight (g)	101.50 a	101.50 a
No. of beetles produced	5.10 a	12.50 a
No. beetles/gram carcass wt.	0.072 a	0.176 a
Weight (g)/beetle	0.48 a	0.51 a
Estimated total brood weight (g)	3.67 a	9.55 a
Brood weight (g)/carcass weight (g)	0.04 a	0.09 a
Male-female ratio/brood	0.92 a	0.91 a

No statistics were performed as responses in the chlorophacinone were essentially equal to or better than control beetles

No significant differences were found in any of the measured or calculated responses between the treatment and control groups in the second part of the second phase of the study (subsequent ability of adults fed no-choice diets to brood and produce normal progeny). The following variables were evaluated: quail carcass weight (in grams), number of beetles produced/brood, number of beetles/carcass weight, weight/beetle, estimated total brood weight/brood, brood weight/carcass weight, male-female ratio/brood, and proportion of males/brood. The study states that the authors believed that the lower number of broods produced in this experiment, relative to

the first which used rat carcasses, may be due to either the age of the beetles and/or the use of a different type/condition of carcass.

D. VERIFICATION OF STATISTICAL RESULTS: The Excel spreadsheet with replicate response results for Phase I had statistical results based on using a paired t-test and the assumption of equal variance. The study design is not a paired design (*i.e.*, a given male-female replicate pair was not tested on both a control carcass and a chlorophacinone carcass), and the assumption of equal variance is not appropriate for several of the variables. Therefore the reviewer reanalyzed the Phase I results using one-sided nonpaired t-tests and the assumption of unequal variance for all analyses except the male/female ratio where the concern was for detecting an increase or decrease as compared to the control. Statistical analysis is provided in Appendix I of this DER. The reviewer agreed that a statistical analysis was not needed for determining if there was increased mortality during Phase II-Part 1 as mortality was lower in the chlorophacinone treatment than controls and that no statistical analysis was needed for Phase II-Part 2 as mean responses in the chlorophacinone group were equal to or better than the control.

There was some discussion in the study report that the number of emerged beetles in the chlorophacinone treated rat carcasses may be attributable to the significant lower rat carcass weights of the chlorophacinone group (mean carcass size = 89.65 grams) as compared to the control group (mean carcass size = 102.80 grams). While an examination of the literature showed a relationship of carcass weight with number of emerged beetles for *N. orbicollis*, this was in the range of between about 7 to 30 gram carcass weights (Trumbo and Fernandez 1995). The number of emerged beetles in the control rats was comparable to the findings in other studies for carcass weights around 30 grams (Trumbo and Fernandez 1995). Therefore, effects caused by carcass size are not expected in this study.

E. STUDY DEFICIENCIES: The study lacks critical test protocol information. In addition, raw data sheets were not provided. Summarized results for replicates were provided in Excel spreadsheets but without raw data sheets these could not be independently verified. An independent statistical analysis conducted using these results found study conclusions that differed in part from those in the study report. Furthermore, the study, which was conducted at a university laboratory, was not conducted under 40 CFR Part 160 Good Laboratory Practices (GLP). Finally, no analysis was made of chlorophacinone residue levels in rat carcasses.

F. REVIEWER'S COMMENTS: This study is classified as Supplemental/Non-guideline. It can be used semi-quantitatively and provides useful information regarding effects of chlorophacinone on non-target insects.

G. CONCLUSIONS: EFED concludes that the study provides useful information regarding effects of chlorophacinone on non-target insects. The lack of effects on beetle production when adults are exposed to chlorophacinone but their larvae are not and reduced number of emerged beetles when larvae are exposed to chlorophacinone but adults are not until brooding of young indicate that larvae are more sensitive to chlorophacinone than adults. Other than larval survival,

no effects on adult survival, fecundity, larval growth or male-female sex ratio were detected at environmental levels.

III. REFERENCES:

Creighton, J.C. 2005. Population density, body size, and phenotypic plasticity of brood size in a burying beetle. Behavioral Ecology 16:1031-1036.

Szalanski, A.L., D.S. Sikes, R. Bischof, M. Fritz. 2000. Population genetics and phylogenetics of the endangered American Burying Beetle, *Nicrophorus americanus* (Coleoptera: Silphidae). Annals of the Entomological Society of America 93 (3): 589-594.

Trumbo, S.T. and A.G. Fernandez. 1995. Regulation of brood size by male parents and cues employed to assess resource size by burying beetles. Ethology Ecology & Evolution 7:313-322.

Data Evaluation Repo[redacted] the toxicity effects of chlorophaci[redacted] TEP on a species of burying beetle, *Nicrophorus orbicollis*

EPA MRID Number 473830-01

Appendix I. Results of Independent Verification of Statistical Results for Phase I of Study

Rat Carcass weight, nonpaired t-test, assume unequal variance:

	control	*chlorophacinone*
Mean	102.8	89.65
Variance	30.800	53.6079
Observations	20	20
Hypothesized Mean Difference	0	
df	35	
t Stat	6.401	
P(T<=t) one-tail	1.1E-07	
t Critical one-tail	1.690	

Chlorophacinone rat carcasses are significantly (P<0.001) smaller than control carcasses.

Number of Emerged Beetles, nonpaired t-test, assume unequal variance:

	control	*chlorophacinone*
Mean	22.5	12.75
Variance	152.053	91.4605
Observations	20	20
Hypothesized Mean Difference	0	
df	36	
t Stat	2.794	
P(T<=t) one-tail	0.0041	
t Critical one-tail	1.688	

Chlorophacinone rat carcasses have significantly (P<0.01) fewer emerged beetles than control carcasses.

No. beetles/gram carcass wt., nonpaired t-test, assume unequal variance:

	control	*chlorophacinone*
Mean	0.21	0.14
Variance	0.0130	0.0108
Observations	20	20
Hypothesized Mean Difference	0	
df	38	
t Stat	2.064	
P(T<=t) one-tail	0.023	
t Critical one-tail	1.686	

Chlorophacinone rat carcasses have significantly (P=0.02) fewer emerged beetles per gram of carcass wt

Average weight (g) per beetle, nonpaired t-test, assume unequal variance:

	control	*chlorophacinone*
Mean	0.404	0.416
Variance	0.0024	0.0033
Observations	19	18
Hypothesized Mean Difference	0	
df	34	
t Stat	-0.668	
P(T<=t) one-tail	0.254	
t Critical one-tail	1.691	

Emerged beetles in chlorophacinone rat carcasses are not significantly (P>0.05) smaller in weight than control beetles

Total mass of emerged beetles, nonpaired t-test, assume unequal variance:

	control	*chlorophacinone*
Mean	9.19	5.24
Variance	26.605	14.372
Observations	20	20
Hypothesized Mean Difference	0	
df	35	
t Stat	2.761	
P(T<=t) one-tail	0.005	
t Critical one-tail	1.690	

Chlorophacinone rat carcasses have significantly (P=0.005) less biomass of beetles produced than controls

Brood wt. (g)/g carcass, nonpaired t-test, assume unequal variance:

	control	*chlorophacinone*
Mean	0.089	0.059
Variance	0.00235	0.00166
Observations	20	20
Hypothesized Mean Difference	0	
df	37	
t Stat	2.124	
P(T<=t) one-tail	0.020	
t Critical one-tail	1.687	
P(T<=t) two-tail	0.040	
t Critical two-tail	2.026	

Chlorophacinone rat carcasses have significantly (P=0.02) less biomass of beetles produced per gram of carcass wt than the controls

Data Evaluation Repo[redacted] the toxicity effects of chlorophaci[redacted] TEP on a species of burying beetle, *Nicrophorus orbicollis*

EPA MRID Number 473830-01

Male/Female Ratio, nonpaired t-test, assume unequal variance:

	control	*chlorophacinone*
Mean	1.0	1.4
Variance	0.243	0.989
Observations	19	18
Hypothesized Mean Difference	0	
df	25	
t Stat	-1.475	
P(T<=t) one-tail	0.076	
t Critical one-tail	1.708	
P(T<=t) two-tail	0.153	
t Critical two-tail	2.060	

Male/Female ratio in chlorophacinone rat carcasses was not significantly different from (P=0.15) the controls

LIPHATECH

3600 WEST ELM STREET
MILWAUKEE, WI 53209
Tel: 414/351 1476 800/351 1476
Fax: 414/247 8166

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, D.C. 20460-0001

August 15, 2011

Re: Final printed label **7173-286 Rozol Prairie Dog Bait**

Dear Sir or Madam,

Please find enclosed the final printed label for the above mentioned pesticide product. Contact me immediately if there is any question regarding this label.

Sincerely,

Michele Brunlinger

Michele Brunlinger
Compliance Specialist
Liphatech, Inc.
3600 West Elm Street
Milwaukee, WI 53209
(414) 410-7235 phone

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

CAUTION: Harmful if swallowed or absorbed through the skin because it may reduce the clotting ability of blood and cause bleeding. Keep away from children, domestic animals and pets. Do not get in eyes on skin or on clothing. All handlers (including applicators) must wear shoes plus socks, and gloves. Any person who retrieves carcasses or unused bait following application of this product must wear gloves.

USER SAFETY REQUIREMENTS: Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands thoroughly after applying bait and before eating, drinking , chewing gum, using tobacco or using the toilet and change into clean clothing.

FIRST AID: Have label when obtaining treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor.

If on skin: Take off contaminated clothing. Rinse skin with plenty of cool water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

TREATMENT FOR PET POISONING: If animal eats bait, call veterinarian at once.

NOTE TO PHYSICIAN OR VETERINARIAN: Anticoagulant Chlorophacinone: If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. **For humans or dogs** that have ingested this product and/or have obvious poisoning symptoms (bleeding or prolonged prothrombin times), give Vitamin K_1 intramuscularly or orally.

ENVIRONMENTAL HAZARDS: This product is toxic to fish and wildlife. Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten this bait. Do not apply directly to water, or to areas where surface water is present. Do not contaminate water by cleaning of equipment or disposal of wastes. Runoff also may be hazardous to aquatic organisms in water adjacent to treated areas.

ENDANGERED SPECIES CONSIDERATIONS: NOTICE: It is a Federal offense to use any pesticide in a manner that results in the death of an endangered species. Use of this product may pose a hazard to endangered or threatened species. Do not use this product within prairie dog towns in the range of the black-footed ferret without first contacting endangered species specialists at a U.S. Fish and Wildlife Service office. Applicators may obtain information regarding the occurrence of endangered species and use limitations for this product by calling EPA's "Endangered Species Hotline" at 1-800-447-3813 to obtain an "Interim Measures" pamphlet for your county. You may also consult your local agricultural extension office or state pesticide lead agency to determine if there are any requirements for use of this product.

EPA Reg. No. 7173-286 Product No. 84111
EPA Est. No. 7173-WI-1 Label No. 150-5035-0811

RESTRICTED USE PESTICIDE

DUE TO HAZARD TO NONTARGET ORGANISMS

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification.

NOT REVIEWED
...ance with PR Notice 82-2
... Draft Labeling Dated
AUG - 8 2011

rozol®

PRAIRIE DOG BAIT

Active Ingredient: chlorophacinone	0.005%
Inert Ingredients	99.995%
Total	100.000%

EPA Reg. No. 7173-286 EPA Est. No. 7173-WI-1

KEEP OUT OF REACH OF CHILDREN

CAUTION: See side panel for additional precautionary statements.

LIPHATECH®

Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209
(414) 351-1476

NET WEIGHT: 30 lbs. PAIL

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL and follow all use directions and precautions. Only use for sites, pests, and application methods specified on this label.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Dispose of product container, unused, spoiled and unconsumed bait as specified on this label.

Use restrictions: This product may only be used as follows:

1. Sites/Pests: Black-Tailed Prairie Dogs *(Cynomys ludovicianus)* on rangeland and adjacent noncrop areas.

2. States: Colorado, Kansas, Nebraska, Oklahoma, Texas and Wyoming.

3. Application Method: Hand application of bait, at least 6 inches down prairie dog burrows. This product may only be used in underground applications. **Do not apply bait on or above ground level. Treat only active burrows.**

4. Treatment Period: Apply between October 1 and March 15 of the following year, when animals will most readily take the grain bait.

5. Non-Applicators: Do not allow children, pets, domestic animals or persons not involved in the application to be in the area where the product is being applied.

6. Grazing Restriction: Do not allow livestock to graze in treated areas for 14 days after treatment and when no bait is found above ground.

Site Assessment: Before applying this product, identify active prairie dog burrows by visual observation. The openings of active burrows will generally be free of leaves, seeds, other debris or spider webs, and will show freshly turned earth, and have prairie dog feces nearby.

Application: Apply 1/4 cup (53 grams or nearly 2 ounces) of bait at least 6 inches down active prairie dog burrows. **Make sure no bait is left on the soil surface at the time of application.** Applicator must retrieve and dispose of any bait that is spilled above ground or placed less than 6 inches down the burrow entrance.

Follow-up: Prairie dogs that have eaten this bait will begin to die off in 4 to 5 days after they eat a lethal amount. The applicator must return to the site within 4 days after bait application, and at 1 to 2 day intervals, to collect and properly dispose of any bait or dead or dying prairie dogs found on the surface. All carcasses found above ground must be collected and disposed of properly. Continue to collect and dispose of dead or dying prairie dogs and search for nontarget animals for at least two weeks, but longer if carcasses are still being found at that time. Carcass collections should occur in late afternoon, near sundown, to reduce the potential of nocturnal animals finding carcasses and dying animals. Bury carcasses on site in holes dug at least 18 inches deep or in inactive burrows (no longer being used by prairie dogs or other species) to avoid non-target animal scavenging. Burial includes covering and packing the hole or burrow with soil. If burial is not practical (due to frozen ground, etc) and other disposal methods are allowed by state and local authorities, collected carcasses may be disposed of by such other methods as insure that the carcasses are inaccessible to scavengers.

Reapplication: If prairie dog activity persists several weeks or months after the bait was applied, a second application may be made, by treating burrows in the same manner, time period and procedure as the first application. Follow all application, site assessment and follow-up directions and use restrictions as found above.

WARRANTY: To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material when such use and/or handling is contrary to label instructions. (072811)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals.

Pesticide Disposal: Wastes resulting from the use of this product may be placed in trash or delivered to an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Dispose of empty container by placing in trash, at an approved waste disposal facility or by incineration or, if allowed by state and local authorities, by burning. If burned stay out of smoke.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

AUG - 8 2011

Mr. Thomas Schmit
Liphatech
3600 West Elm Street
Milwaukee, WI 53209

Dear Mr. Schmitt:

Subject: Label Amendment; Revised Directions for Use
Rozol Prairie Dog Bait
EPA Reg. No.: 7173- 286
Your Application Dated: July 29, 2011

The proposed labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable. A stamped copy is enclosed for your records. Please submit two copies of your final printed labeling before you release the product for shipment.

EPA is approving this amendment request pursuant to the order of the United States District Court for the District of Columbia. See *Defenders of Wildlife v. Jackson*, No. 09-cv-1814, July 27, 2011 Order. Approval of this label amendment does not affect any of the modified conditions of registration listed in EPA's October 29, 2009 letter to you. Any unfilled conditions of registration listed in the letter are still applicable.

If you have any questions, please contact me by phone at: (703) 308-6249, or by email at: hebert.john@epa.gov.

Regards,

John Hebert, PM 7
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

CAUTION: Harmful if swallowed or absorbed through the skin because it may reduce the clotting ability of blood and cause bleeding. Keep away from children, domestic animals and pets. Do not get in eyes on skin or on clothing. All handlers (including applicators) must wear shoes plus socks, and gloves. Any person who retrieves carcasses or unused bait following application of this product must wear gloves.

USER SAFETY REQUIREMENTS: Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands thoroughly after applying bait and before eating, drinking , chewing gum, using tobacco or using the toilet and change into clean clothing.

FIRST AID: Have label when obtaining treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor.

If on skin: Take off contaminated clothing. Rinse skin with plenty of cool water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

TREATMENT FOR PET POISONING: If animal eats bait, call veterinarian at once.

NOTE TO PHYSICIAN OR VETERINARIAN: Anticoagulant Chlorophacinone: If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. For humans or dogs that have ingested this product and/or have obvious poisoning symptoms (bleeding or prolonged prothrombin times), give Vitamin K_1 intramuscularly or orally.

ENVIRONMENTAL HAZARDS: This product is toxic to fish and wildlife. Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten this bait. Do not apply directly to water, or to areas where surface water is present. Do not contaminate water by cleaning of equipment or disposal of wastes. Runoff also may be hazardous to aquatic organisms in water adjacent to treated areas.

ENDANGERED SPECIES CONSIDERATIONS: NOTICE: It is a Federal offense to use any pesticide in a manner that results in the death of an endangered species. Use of this product may pose a hazard to endangered or threatened species. Do not use this product within prairie dog towns in the range of the black-footed ferret without first contacting endangered species specialists at a U.S. Fish and Wildlife Service office. Applicators may obtain information regarding the occurrence of endangered species and use limitations for this product by calling EPA's "Endangered Species Hotline" at 1-800-447-3813 to obtain an "Interim Measures" pamphlet for your county. You may also consult your local agricultural extension office or state pesticide lead agency to determine if there are any requirements for use of this product.

RESTRICTED USE PESTICIDE

DUE TO HAZARD TO NONTARGET ORGANISMS

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification.

Active Ingredient: chlorophacinone	0.005%
Inert Ingredients	99.995%
Total	100.000%

EPA Reg. No. 7173-286 EPA Est. No. 7173-WI-1

KEEP OUT OF REACH OF CHILDREN

CAUTION: See side panel for additional precautionary statements.

LIPHATECH®

Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209
(414) 351-1476

ACCEPTED
AUG - 8 2011

NET WEIGHT:

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:

EPA. Reg. No: 7173-286

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL and follow all use directions and precautions. Only use for sites, pests, and application methods specified on this label.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Dispose of product container, unused, spoiled and unconsumed bait as specified on this label.

Use restrictions: This product may only be used as follows:

1. Sites/Pests: Black-Tailed Prairie Dogs *(Cynomys ludovicianus)* on rangeland and adjacent noncrop areas.

2. States: Colorado, Kansas, Nebraska, Oklahoma, Texas and Wyoming.

3. Application Method: Hand application of bait, at least 6 inches down prairie dog burrows. This product may only be used in underground applications. Do not apply bait on or above ground level. Treat only active burrows.

4. Treatment Period: Apply between October 1 and March 15 of the following year, when animals will most readily take the grain bait.

5. Non-Applicators: Do not allow children, pets, domestic animals or persons not involved in the application to be in the area where the product is being applied.

6. Grazing Restriction: Do not allow livestock to graze in treated areas for 14 days after treatment and when no bait is found above ground.

Site Assessment: Before applying this product, identify active prairie dog burrows by visual observation. The openings of active burrows will generally be free of leaves, seeds, other debris or spider webs, and will show freshly turned earth, and have prairie dog feces nearby.

Application: Apply 1/4 cup (53 grams or nearly 2 ounces) of bait at least 6 inches down active prairie dog burrows. Make sure no bait is left on the soil surface at the time of application. Applicator must retrieve and dispose of any bait that is spilled above ground or placed less than 6 inches down the burrow entrance.

Follow-up: Prairie dogs that have eaten this bait will begin to die off in 4 to 5 days after they eat a lethal amount. The applicator must return to the site within 4 days after bait application, and at 1 to 2 day intervals, to collect and properly dispose of any bait or dead or dying prairie dogs found on the surface. All carcasses found above ground must be collected and disposed of properly. Continue to collect and dispose of dead or dying prairie dogs and search for nontarget animals for at least two weeks, but longer if carcasses are still being found at that time. Carcass collections should occur in late afternoon, near sundown, to reduce the potential of nocturnal animals finding carcasses and dying animals. Bury carcasses on site in holes dug at least 18 inches deep or in inactive burrows (no longer being used by prairie dogs or other species) to avoid non-target animal scavenging. Burial includes covering and packing the hole or burrow with soil. If burial is not practical (due to frozen ground, etc) and other disposal methods are allowed by state and local authorities, collected carcasses may be disposed of by such other methods as insure that the carcasses are inaccessible to scavengers.

Reapplication: If prairie dog activity persists several weeks or months after the bait was applied, a second application may be made, by treating burrows in the same manner, time period and procedure as the first application. Follow all application, site assessment and follow-up directions and use restrictions as found above.

WARRANTY: To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material when such use and/or handling is contrary to label instructions. (072811)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. **Pesticide Storage:** Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals. **Pesticide Disposal:** Wastes resulting from the use of this product may be placed in trash or delivered to an approved waste disposal facility. **Container Handling:** Nonrefillable container. Do not reuse or refill this container. Dispose of empty container by placing in trash, at an approved waste disposal facility or by incineration or, if allowed by state and local authorities, by burning. If burned stay out of smoke.

SUMMARY: As of August 8, 2011, it is a violation of Federal law to use Rozol Prairie Dog Bait in the states of Montana, New Mexico, North Dakota, and South Dakota. This is the case even though existing stocks of Rozol Prairie Dog Bait may bear labeling for these states. No person may sell or distribute such existing stocks to a retail customer unless a copy of this order is first provided to the customer. Other transfers of such existing stocks also require providing a copy of this order to the recipient, as described in the order.

US Environmental Protection Agency
Office of Pesticide Programs

Final Cancellation Order for Rozol Prairie Dog Bait Labeled For Use in Montana, New Mexico, North Dakota, and South Dakota

August 8, 2011

Electronically available at:
http:/www.epa.gov/pesticides/regulating/rozol.html

Final Cancellation Order for Rozol Prairie Dog Bait Labeled for Use in Montana, New Mexico, North Dakota, and South Dakota

Background

On July 27, 2011, the U.S. District Court for the District of Columbia issued an order requiring EPA to take certain measures respecting the registration of Rozol Prairie Dog Bait (EPA Reg. No. 7173-286), pending the completion of endangered species consultation between EPA and the United States Fish and Wildlife Service regarding this product. *See Defenders of Wildlife v. Jackson*, No. 09-cv-1814, July 27, 2011.

Pursuant to court order, on August 8, 2011, EPA approved an application from the product registrant (Liphatech) to amend the label for this product. The label amendment removed Montana, New Mexico, North Dakota, and South Dakota from the list of states where use is authorized. The Court also directed EPA to issue an immediately effective cancellation order respecting Rozol Prairie Dog Bait labeled for use in Montana, New Mexico, North Dakota, and South Dakota, to address any existing stocks of such product.

Neither of these actions limit use of Rozol Prairie Dog Bait, consistent with product labeling, in the remaining six states: Colorado, Kansas, Nebraska, Oklahoma, Texas, and Wyoming.

Liphatech may not sell or distribute existing stocks in its possession and control unless they have been relabeled, in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and its implementing regulations, to eliminate the portion of the labeling authorizing use in Montana, New Mexico, North Dakota, and South Dakota. See Paragraph 3 of this order. Once such existing stocks are relabeled consistent with Paragraph 3 of this order, they are no longer existing stocks subject to this order. See the definition of "existing stocks" in Paragraph 2.

Existing stocks that have not been relabeled to eliminate the portions of the labeling authorizing use in Montana, New Mexico, North Dakota, and South Dakota (in accordance with FIFRA and its implementing regulations) are subject to a separate provision of this cancellation order (Paragraph 4), which establishes, independent of the labeling, a FIFRA prohibition on use in these four states. Paragraph 4 furthermore restricts the conditions under which such existing stocks may be sold or distributed. One particular restriction on the sale and distribution of such existing stocks (Paragraph 4.C.) applies even outside of Montana, New Mexico, North Dakota, and South Dakota.

Finally, this order makes clear that it is not based on an EPA determination under FIFRA section 6(b), and does not trigger the procedural requirements at 40 CFR Part 164 Subpart D in the event that EPA later receives an application to amend the label for Rozol Prairie Dog Bait, to add Montana, New Mexico, North Dakota, and South Dakota back to the label. Pursuant to the directions of the Court, EPA is issuing this cancellation order, effective immediately, under FIFRA section 6(a).

Final Cancellation Order

1. Pursuant to section 6(a)(1) of FIFRA and the July 27, 2011 order of the U.S. District Court for the District of Columbia, EPA hereby issues a final cancellation order for Rozol Prairie Dog Bait (EPA Registration No. 7173-286) that is labeled for use in Montana, New Mexico, North Dakota, and South Dakota. Any distribution, sale, or use of existing stocks in a manner inconsistent with this order will be considered a violation of FIFRA sections 12(a)(2)(K) and/or 12(a)(1)(A). This order is immediately effective and will remain in effect unless and until it is amended.

2. For purposes of this order, the term "existing stocks," is defined, consistent with EPA's existing stocks policy (56 FR 29362, June 26, 1991) as those stocks of Rozol Prairie Dog Bait labeled for use in Montana, New Mexico, North Dakota, and South Dakota that are currently in the United States and which were packaged, labeled, and released for shipment prior to the August 8, 2011 label amendment to delete use in Montana, New Mexico, North Dakota, and South Dakota.

3. Liphatech may not sell or distribute existing stocks within its possession or control unless those stocks have been labeled in accordance with FIFRA and its implementing regulations to prohibit use in Montana, New Mexico, North Dakota, and South Dakota.

4. With respect to existing stocks bearing labels indicating that use in Montana, New Mexico, North Dakota, and South Dakota is allowed:

   A. No person may use such existing stocks in Montana, New Mexico, North Dakota, or South Dakota.

   B. No person may sell or distribute such existing stocks in Montana, New Mexico, North Dakota, and South Dakota, unless such sale or distribution is for the purpose of disposal, returning the material to the person from whom it was purchased, or for transfer for the purpose of resale outside of Montana, New Mexico, North Dakota, or South Dakota.

   C. No person may sell or distribute such existing stocks to another person unless, for each such transfer, a copy of this order is provided to such other person at or before the time of the transfer and, additionally, another copy is shipped with the stocks if they are transported by a third party.

   D. Distribution or sale of such existing stocks, except as prohibited under paragraphs 4.B and 4.C., is permitted until such stocks are depleted. No person may use such existing stocks in a manner that is inconsistent with the previously-approved product labeling.

5. This cancellation order is not based on any determination by EPA under FIFRA section 6(b), or on a final cancellation order as that term is used in 40 CFR 164.130.

Lois Rossi

Lois Rossi
Director, Registration Division

August 8, 2011
Date

LIPHATECH

3600 WEST ELM STREET
MILWAUKEE, WI 53209
Tel: 414/351 1476 800/351 1476
Fax: 414/247 8166

Document Processing Desk
EPA Office of Pesticide Programs (7504P)
One Potomac Yard, Room S4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: John Hebert / Rosanna Louie-Juzwiak

July 29, 2011

Re: Application for amendment to
"Rozol Prairie Dog Bait" EPA Reg. No. 7173-286

Dear Sir or Madam,

The enclosed amendment application is submitted in order to modify the product label, as required by the "order on remedy" issued by the US District Court in case 1:09-cv-01814-ESH Defenders of Wildlife v. Jackson and EPA (copy of order is attached). We believe that this action does not fall into any PRIA category and requires no fee.

The label submitted with this application removes the states of Montana, North Dakota, South Dakota and New Mexico from the label's list of states where the product may be used. As required by the District Court order, we have included in this submission package a copy of the previously approved product label, with the changed elements demarcated. Please note that I have also marked the changed "version number" that we use internally for tracking of labels. This is a non-FIFRA element and does not change the label content.

Thank you for your attention to this matter. Please contact me directly if there is any problem or question concerning this submission.

Sincerely,

Thomas Schmit
Manager of Regulatory Affairs

LiphaTech Home Page: http//www.liphatech.com
E-mail: rodentcontrol@liphatech.com

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [x] Amendment
- [ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
7173-286	John Hebert	[ ] None [x] Restricted
4. Company/Product (Name) Rozol Prairie Dog Bait	**PM#** Insecticide/Rodenticide Branch	

5. Name and Address of Applicant *(Include ZIP Code)*

Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [x] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application is submitted in order to amend the product label by removing the states of Montana, North Dakota, South Dakota and New Mexico from the label's listing of states where this product may be used, as required by the "order on remedy" issued by the US District Court in case 1:09-cv-01814-ESH Defenders of Wildlife v. Jackson and EPA (copy of order attached). We believe this is a non-PRIA amendment that requires no fee. Please contact Thomas Schmit at 414-410-7230, or schmitt@liphatech.com with any questions or concerns.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [x] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	1 pound up to 2000 pounds	[✓] On label

6. Manner in Which Label is Affixed to Product [x] Lithograph [x] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas Schmit	Manager of Regulatory Affairs	(414) 410-7230

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Thomas Schmit	Manager of Regulatory Affairs
4. Typed Name Thomas Schmit	**5. Date** 8/1/2011

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PRECAUTIONARY STATEMENTS
Hazard to Humans and Domestic Animals

CAUTION: Harmful if swallowed or absorbed through the skin because it may reduce the clotting ability of blood and cause bleeding. Keep away from children, domestic animals and pets. Do not get in eyes on skin or on clothing. All handlers (including applicators) must wear shoes plus socks, and gloves. Any person who retrieves carcasses or unused bait following application of this product must wear gloves.

USER SAFETY REQUIREMENTS: Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands thoroughly after applying bait and before eating, drinking , chewing gum, using tobacco or using the toilet and change into clean clothing.

FIRST AID: Have label when obtaining treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor.

If on skin: Take off contaminated clothing. Rinse skin with plenty of cool water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

TREATMENT FOR PET POISONING: If animal eats bait, call veterinarian at once.

NOTE TO PHYSICIAN OR VETERINARIAN: Anticoagulant Chlorophacinone: If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. For humans or dogs that have ingested this product and/or have obvious poisoning symptoms (bleeding or prolonged prothrombin times), give Vitamin K_1 intramuscularly or orally.

ENVIRONMENTAL HAZARDS: This product is toxic to fish and wildlife. Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten this bait. Do not apply directly to water, or to areas where surface water is present. Do not contaminate water by cleaning of equipment or disposal of wastes. Runoff also may be hazardous to aquatic organisms in water adjacent to treated areas.

ENDANGERED SPECIES CONSIDERATIONS: NOTICE: It is a Federal offense to use any pesticide in a manner that results in the death of an endangered species. Use of this product may pose a hazard to endangered or threatened species. Do not use this product within prairie dog towns in the range of the black-footed ferret without first contacting endangered species specialists at a U.S. Fish and Wildlife Service office. Applicators may obtain information regarding the occurrence of endangered species and use limitations for this product by calling EPA's "Endangered Species Hotline" at 1-800-447-3813 to obtain an "Interim Measures" pamphlet for your county. You may also consult your local agricultural extension office or state pesticide lead agency to determine if there are any requirements for use of this product.

EPA Reg. No. 7173-286 Product No. 84111
EPA Est. No. 7173-WI-1 Label No. 150-5035-0711

RESTRICTED USE PESTICIDE
DUE TO HAZARD TO NONTARGET ORGANISMS
For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification.

Current label as approved on 9/10/10

4 states deleted

rozol®
PRAIRIE DOG BAIT

Active Ingredient: chlorophacinone	0.005%
Inert Ingredients	99.995%
Total	100.000%

EPA Reg. No. 7173-286 EPA Est. No. 7173-WI-1

KEEP OUT OF REACH OF CHILDREN
CAUTION: See side panel for additional precautionary statements.

LIPHATECH®
Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209
(414) 351-1476

NET WEIGHT: 30 lbs. PAIL

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **READ THIS LABEL** and follow all use directions and precautions. Only use for sites, pests, and application methods specified on this label.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Dispose of product container, unused, spoiled and unconsumed bait as specified on this label.

Use restrictions: This product may only be used as follows:

1. **Sites/Pests:** Black-Tailed Prairie Dogs *(Cynomys ludovicianus)* on rangeland and adjacent noncrop areas.
2. **States:** Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas and Wyoming.
3. **Application Method:** Hand application of bait, at least 6 inches down prairie dog burrows. This product may only be used in underground applications. **Do not apply bait on or above ground level. Treat only active burrows.**
4. **Treatment Period:** Apply between October 1 and March 15 of the following year, when animals will most readily take the grain bait.
5. **Non-Applicators:** Do not allow children, pets, domestic animals or persons not involved in the application to be in the area where the product is being applied.
6. **Grazing Restriction:** Do not allow livestock to graze in treated areas for 14 days after treatment and when no bait is found above ground.

Site Assessment: Before applying this product, identify active prairie dog burrows by visual observation. The openings of active burrows will generally be free of leaves, seeds, other debris or spider webs, and will show freshly turned earth, and have prairie dog feces nearby.

Application: Apply 1/4 cup (53 grams or nearly 2 ounces) of bait at least 6 inches down active prairie dog burrows. **Make sure no bait is left on the soil surface at the time of application.** Applicator must retrieve and dispose of any bait that is spilled above ground or placed less than 6 inches down the burrow entrance.

Follow-up: Prairie dogs that have eaten this bait will begin to die off in 4 to 5 days after they eat a lethal amount. The applicator must return to the site within 4 days after bait application, and at 1 to 2 day intervals, to collect and properly dispose of any bait or dead or dying prairie dogs found on the surface. All carcasses found above ground must be collected and disposed of properly. Continue to collect and dispose of dead or dying prairie dogs and search for nontarget animals for at least two weeks, but longer if carcasses are still being found at that time. Carcass collections should occur in late afternoon, near sundown, to reduce the potential of nocturnal animals finding carcasses and dying animals. Bury carcasses on site in holes dug at least 18 inches deep or in inactive burrows (no longer being used by prairie dogs or other species) to avoid non-target animal scavenging. Burial includes covering and packing the hole or burrow with soil. If burial is not practical (due to frozen ground, etc) and other disposal methods are allowed by state and local authorities, collected carcasses may be disposed of by such other methods as insure that the carcasses are inaccessible to scavengers.

Reapplication: If prairie dog activity persists several weeks or months after the bait was applied, a second application may be made, by treating burrows in the same manner, time period and procedure as the first application. Follow all application, site assessment and follow-up directions and use restrictions as found above.

WARRANTY: To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material when such use and/or handling is contrary to label instructions.

(081910a)

New version number

STORAGE AND DISPOSAL
Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals.

Pesticide Disposal: Wastes resulting from the use of this product may be placed in trash or delivered to an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Dispose of empty container by placing in trash, at an approved waste disposal facility or by incineration or, if allowed by state and local authorities, by burning. If burned stay out of smoke.

LIPHATECH

3600 WEST ELM STREET
MILWAUKEE, WI 53209
Tel: 414/351 1476 800/351 1476
Fax: 414/247 8166

484102-00

Document Processing Desk
EPA Office of Pesticide Programs (7504P)
One Potomac Yard, Room S4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: John Hebert, Insecticide/Rodenticide Branch

March 1, 2011

Re: Additional information concerning
"Rozol Prairie Dog Bait" EPA Reg. No. 7173-286

Dear Mr. Hebert,

The enclosed study is submitted in support of our product "Rozol Prairie Dog Bait," EPA Reg. No. 7173-286. The study was designed to gather factual data concerning the availability of "intoxicated" prairie dogs on the surface of the ground following application of the Rozol bait product. The study found no intoxicated prairie dogs (and no prairie dog carcasses) on the ground surface for the three weeks following a commercial bait application at that specific site, at that specific time.

This information is relevant to the EPA's consultation with US Fish and Wildlife Service concerning the registration of Rozol Prairie Dog Bait, pursuant to EPA's "Chlorophacinone Effects Determination" dated September 29, 2010 and published on EPA's website. As such, we request that this study also be forwarded by EPA to the US FWS, for use in their review process.

Thank you for your attention to this matter. Please contact me directly if there is any problem or question concerning this submission.

Sincerely,

Thomas Schmit
Manager of Regulatory Affairs

cc: Ms. Melissa Grable, EPA Environmental Fate and Effects Division

LIPHATECH

3600 WEST ELM STREET
MILWAUKEE, WI 53209
Tel: 414/351 1476 800/351 1476
Fax: 414/247 8166

TRANSMITTAL DOCUMENT

Name and address of Submitter:

Liphatech, Inc., 3600 W. Elm Street, Milwaukee, WI 53209

Regulatory Action in Support of Which this Package is Submitted:

Rozol Prairie Dog Bait, EPA Reg. No. 7173- 286

Transmittal Date: **March 1, 2011**

List of Submitted Studies:

Volume 1: Administrative materials
- Cover letter dated March 1, 2011

48410201 **Volume 2: Rozol Prairie Dog Bait: Availability of "Intoxicated" Prairie Dogs**
(Guideline number none) (LTI Number 10005)

Company Official: Thomas Schmit

Thomas Schmit, Manager of Regulatory Affairs
Liphatech, Inc., 3600 W. Elm Street, Milwaukee, WI 53209
phone (414) 410-7230
fax (414) 247-8172
e-mail schmitt@liphatech.com

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 10, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

THOMAS SCHMIT
LIPHATECH, INC.
3600 W. ELM STREET
MILWAUKEE, WI 53209

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 04-MAR-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Decision # 439 928

SEP 10 2010

300 5.88 2389
1155 5-876962

Mr. Thomas Schmit
Liphatech, Inc.
3600 West Elm Street
Milwaukee, WI 53209

Dear Mr. Schmit:

Subject: Labeling Amendment; Revised Directions for Use
Rozol Prairie Dog Bait
EPA Registration No. 7173-286
Label submitted via E-mail on August 20, 2010

The proposed labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable. A stamped copy is enclosed for your records. Please submit one copy of your final printed labeling before you release the product for shipment.

EPA notes that a June 5, 2009 petition has been filed by the World Wildlife Fund, raising questions about whether Rozol meets the standard for registration under FIFRA. The Agency is currently reviewing the questions raised in the petition. EPA is approving this amendment request because the Agency finds that, when compared to the terms of the existing Rozol registration, the amended registration poses less or the same risk to health and the environment and thus, when compared to the existing registration, the amended registration will not result in unreasonable adverse effects on the environment. EPA's grant of this amendment request does not mean that the Agency has resolved the issues raised in the petition or that the amended registration has been found to fully comply with all the requirements of FIFRA. The Agency is continuing to consider the issues raised in the petition, and will as part of that process determine whether the Rozol registration as amended fully complies with FIFRA, or whether additional changes to the terms and conditions of registration (or cancellation of the registration) are appropriate. Approval of this label amendment does not affect any of the modified conditions of registration listed in EPA's October 29, 2009 letter to you. Any unfilled conditions of registration listed in the letter are still applicable.

Sincerely yours,

John Hebert
Product Manager (07)
Insecticide-Rodenticide Branch
Registration Division (7505P)

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

CAUTION: Harmful if swallowed or absorbed through the skin because it may reduce the clotting ability of blood and cause bleeding. Keep away from children, domestic animals and pets. Do not get in eyes on skin or on clothing. All handlers (including applicators) must wear shoes plus socks, and gloves. Any person who retrieves carcasses or unused bait following application of this product must wear gloves.

USER SAFETY REQUIREMENTS: Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands thoroughly after applying bait and before eating, drinking , chewing gum, using tobacco or using the toilet and change into clean clothing.

FIRST AID: Have label when obtaining treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor.

If on skin: Take off contaminated clothing. Rinse skin with plenty of cool water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

TREATMENT FOR PET POISONING: If animal eats bait, call veterinarian at once.

NOTE TO PHYSICIAN OR VETERINARIAN: Anticoagulant Chlorophacinone: If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. **For humans or dogs** that have ingested this product and/or have obvious poisoning symptoms (bleeding or prolonged prothrombin times), give Vitamin K_1 intramuscularly or orally.

ENVIRONMENTAL HAZARDS: This product is toxic to fish and wildlife. Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten this bait. Do not apply directly to water, or to areas where surface water is present. Do not contaminate water by cleaning of equipment or disposal of wastes. Runoff also may be hazardous to aquatic organisms in water adjacent to treated areas.

ENDANGERED SPECIES CONSIDERATIONS: NOTICE: It is a Federal offense to use any pesticide in a manner that results in the death of an endangered species. Use of this product may pose a hazard to endangered or threatened species. Do not use this product within prairie dog towns in the range of the black-footed ferret without first contacting endangered species specialists at a U.S. Fish and Wildlife Service office. Applicators may obtain information regarding the occurrence of endangered species and use limitations for this product by calling EPA's "Endangered Species Hotline" at 1-800-447-3813 to obtain an "Interim Measures" pamphlet for your county. You may also consult your local agricultural extension office or state pesticide lead agency to determine if there are any requirements for use of this product.

RESTRICTED USE PESTICIDE

DUE TO HAZARD TO NONTARGET ORGANISMS

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification.

Active Ingredient: chlorophacinone	0.005%
Inert Ingredients	99.995%
Total	100.000%

EPA Reg. No. 7173-286 EPA Est. No. 7173-WI-1

KEEP OUT OF REACH OF CHILDREN

CAUTION: See side panel for additional precautionary statements.

LIPHATECH®

Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209
(414) 351-1476

NET WEIGHT:

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL and follow all use directions and precautions. Only use for sites, pests, and application methods specified on this label.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Dispose of product container, unused, spoiled and unconsumed bait as specified on this label.

Use restrictions: This product may only be used as follows:

1. **Sites/Pests:** Black-Tailed Prairie Dogs *(Cynomys ludovicianus)* on rangeland and adjacent noncrop areas.
2. **States:** Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas and Wyoming.
3. **Application Method:** Hand application of bait, at least 6 inches down prairie dog burrows. This product may only be used in underground applications. **Do not apply bait on or above ground level. Treat only active burrows.**
4. **Treatment Period:** Apply between October 1 and March 15 of the following year, when animals will most readily take the grain bait.
5. **Non-Applicators:** Do not allow children, pets, domestic animals or persons not involved in the application to be in the area where the product is being applied.
6. **Grazing Restriction:** Do not allow livestock to graze in treated areas for 14 days after treatment and when no bait is found above ground.

Site Assessment: Before applying this product, identify active prairie dog burrows by visual observation. The openings of active burrows will generally be free of leaves, seeds, other debris or spider webs, and will show freshly turned earth, and have prairie dog feces nearby.

Application: Apply 1/4 cup (53 grams or nearly 2 ounces) of bait at least 6 inches down active prairie dog burrows. **Make sure no bait is left on the soil surface at the time of application.** Applicator must retrieve and dispose of any bait that is spilled above ground or placed less than 6 inches down the burrow entrance.

Follow-up: Prairie dogs that have eaten this bait will begin to die off in 4 to 5 days after they eat a lethal amount. The applicator must return to the site within 4 days after bait application, and at 1 to 2 day intervals, to collect and properly dispose of any bait or dead or dying prairie dogs found on the surface. All carcasses found above ground must be collected and disposed of properly. Continue to collect and dispose of dead or dying prairie dogs and search for nontarget animals for at least two weeks, but longer if carcasses are still being found at that time. Carcass collections should occur in late afternoon, near sundown, to reduce the potential of nocturnal animals finding carcasses and dying animals. Bury carcasses on site in holes dug at least 18 inches deep or in inactive burrows (no longer being used by prairie dogs or other species) to avoid non-target animal scavenging. Burial includes covering and packing the hole or burrow with soil. If burial is not practical (due to frozen ground, etc) and other disposal methods are allowed by state and local authorities, collected carcasses may be disposed of by such other methods as insure that the carcasses are inaccessible to scavengers.

Reapplication: If prairie dog activity persists several weeks or months after the bait was applied, a second application may be made, by treating burrows in the same manner, time period and procedure as the first application. Follow all application, site assessment and follow-up directions and use restrictions as found above.

WARRANTY: To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material when such use and/or handling is contrary to label instructions. (081910)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. **Pesticide Storage:** Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals. **Pesticide Disposal:** Wastes resulting from the use of this product may be placed in trash or delivered to an approved waste disposal facility. **Container Handling:** Nonrefillable container. Do not reuse or refill this container. Dispose of empty container by placing in trash, at an approved waste disposal facility or by incineration or, if allowed by state and local authorities, by burning. If burned stay out of smoke.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. Thomas Schmit
Liphatech, Inc.
3600 West Elm Street
Milwaukee, WI 53209

SEP 10 2010

Dear Mr. Schmit:

Subject: Labeling Amendment; Revised Directions for Use
Rozol Prairie Dog Bait
EPA Registration No. 7173-286
Label submitted via E-mail on August 20, 2010

The proposed labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable. A stamped copy is enclosed for your records. Please submit one copy of your final printed labeling before you release the product for shipment.

EPA notes that a June 5, 2009 petition has been filed by the World Wildlife Fund, raising questions about whether Rozol meets the standard for registration under FIFRA. The Agency is currently reviewing the questions raised in the petition. EPA is approving this amendment request because the Agency finds that, when compared to the terms of the existing Rozol registration, the amended registration poses less or the same risk to health and the environment and thus, when compared to the existing registration, the amended registration will not result in unreasonable adverse effects on the environment. EPA's grant of this amendment request does not mean that the Agency has resolved the issues raised in the petition or that the amended registration has been found to fully comply with all the requirements of FIFRA. The Agency is continuing to consider the issues raised in the petition, and will as part of that process determine whether the Rozol registration as amended fully complies with FIFRA, or whether additional changes to the terms and conditions of registration (or cancellation of the registration) are appropriate. Approval of this label amendment does not affect any of the modified conditions of registration listed in EPA's October 29, 2009 letter to you. Any unfilled conditions of registration listed in the letter are still applicable.

Sincerely yours,

John Hebert
Product Manager (07)
Insecticide-Rodenticide Branch
Registration Division (7505P)

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

CAUTION: Harmful if swallowed or absorbed through the skin because it may reduce the clotting ability of blood and cause bleeding. Keep away from children, domestic animals and pets. Do not get in eyes on skin or on clothing. All handlers (including applicators) must wear shoes plus socks, and gloves. Any person who retrieves carcasses or unused bait following application of this product must wear gloves.

USER SAFETY REQUIREMENTS: Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands thoroughly after applying bait and before eating, drinking , chewing gum, using tobacco or using the toilet and change into clean clothing.

FIRST AID: Have label when obtaining treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor.

If on skin: Take off contaminated clothing. Rinse skin with plenty of cool water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

TREATMENT FOR PET POISONING: If animal eats bait, call veterinarian at once.

NOTE TO PHYSICIAN OR VETERINARIAN: Anticoagulant Chlorophacinone: If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. **For humans or dogs** that have ingested this product and/or have obvious poisoning symptoms (bleeding or prolonged prothrombin times), give Vitamin K_1 intramuscularly or orally.

ENVIRONMENTAL HAZARDS: This product is toxic to fish and wildlife. Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten this bait. Do not apply directly to water, or to areas where surface water is present. Do not contaminate water by cleaning of equipment or disposal of wastes. Runoff also may be hazardous to aquatic organisms in water adjacent to treated areas.

ENDANGERED SPECIES CONSIDERATIONS: NOTICE: It is a Federal offense to use any pesticide in a manner that results in the death of an endangered species. Use of this product may pose a hazard to endangered or threatened species. Do not use this product within prairie dog towns in the range of the black-footed ferret without first contacting endangered species specialists at a U.S. Fish and Wildlife Service office. Applicators may obtain information regarding the occurrence of endangered species and use limitations for this product by calling EPA's "Endangered Species Hotline" at 1-800-447-3813 to obtain an "Interim Measures" pamphlet for your county. You may also consult your local agricultural extension office or state pesticide lead agency to determine if there are any requirements for use of this product.

RESTRICTED USE PESTICIDE

DUE TO HAZARD TO NONTARGET ORGANISMS

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification.

Active Ingredient: chlorophacinone	0.005%
Inert Ingredients	99.995%
Total	100.000%

EPA Reg. No. 7173-286 EPA Est. No. 7173-WI-1

KEEP OUT OF REACH OF CHILDREN

CAUTION: See side panel for additional precautionary statements.

LIPHATECH®

Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209
(414) 351-1476

NET WEIGHT:

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL and follow all use directions and precautions. Only use for sites, pests, and application methods specified on this label.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Dispose of product container, unused, spoiled and unconsumed bait as specified on this label.

Use restrictions: This product may only be used as follows:

1. **Sites/Pests:** Black-Tailed Prairie Dogs *(Cynomys ludovicianus)* on rangeland and adjacent noncrop areas.
2. **States:** Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas and Wyoming.
3. **Application Method:** Hand application of bait, at least 6 inches down prairie dog burrows. This product may only be used in underground applications. **Do not apply bait on or above ground level. Treat only active burrows.**
4. **Treatment Period:** Apply between October 1 and March 15 of the following year, when animals will most readily take the grain bait.
5. **Non-Applicators:** Do not allow children, pets, domestic animals or persons not involved in the application to be in the area where the product is being applied.
6. **Grazing Restriction:** Do not allow livestock to graze in treated areas for 14 days after treatment and when no bait is found above ground.

Site Assessment: Before applying this product, identify active prairie dog burrows by visual observation. The openings of active burrows will generally be free of leaves, seeds, other debris or spider webs, and will show freshly turned earth, and have prairie dog feces nearby.

Application: Apply 1/4 cup (53 grams or nearly 2 ounces) of bait at least 6 inches down active prairie dog burrows. **Make sure no bait is left on the soil surface at the time of application.** Applicator must retrieve and dispose of any bait that is spilled above ground or placed less than 6 inches down the burrow entrance.

Follow-up: Prairie dogs that have eaten this bait will begin to die off in 4 to 5 days after they eat a lethal amount. The applicator must return to the site within 4 days after bait application, and at 1 to 2 day intervals, to collect and properly dispose of any bait or dead or dying prairie dogs found on the surface. All carcasses found above ground must be collected and disposed of properly. Continue to collect and dispose of dead or dying prairie dogs and search for nontarget animals for at least two weeks, but longer if carcasses are still being found at that time. Carcass collections should occur in late afternoon, near sundown, to reduce the potential of nocturnal animals finding carcasses and dying animals. Bury carcasses on site in holes dug at least 18 inches deep or in inactive burrows (no longer being used by prairie dogs or other species) to avoid non-target animal scavenging. Burial includes covering and packing the hole or burrow with soil. If burial is not practical (due to frozen ground, etc) and other disposal methods are allowed by state and local authorities, collected carcasses may be disposed of by such other methods as insure that the carcasses are inaccessible to scavengers.

Reapplication: If prairie dog activity persists several weeks or months after the bait was applied, a second application may be made, by treating burrows in the same manner, time period and procedure as the first application. Follow all application, site assessment and follow-up directions and use restrictions as found above.

WARRANTY: To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material when such use and/or handling is contrary to label instructions. (081910)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. **Pesticide Storage:** Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals. **Pesticide Disposal:** Wastes resulting from the use of this product may be placed in trash or delivered to an approved waste disposal facility. **Container Handling:** Nonrefillable container. Do not reuse or refill this container. Dispose of empty container by placing in trash, at an approved waste disposal facility or by incineration or, if allowed by state and local authorities, by burning. If burned stay out of smoke.

EP Reg. No. 7173-286
Thomas Schmit
to:
John Hebert
08/20/2010 12:04 PM
Show Details

History: This message has been forwarded.

Hello Mr. Hebert –

Per our telephone discussion this morning ...
here is the label for Rozol Prairie Dog Bait for our pending amendment.

Thanks –

Tom Schmit
Liphatech, Inc.

RE: proposed amendment to Rozol Prairie Dog Bait label

Thomas Schmit to: Meredith Laws 06/18/2010 04:39 PM

Cc: John Hebert, Lois Rossi, "Carl Tanner", "Al Smith"

History: This message has been forwarded.

Hello Meredith -

Thank you for your prompt review. Here is our response to your comments:

We do not believe it is necessary to "off label" entire counties when black-footed ferrets may be present only in specific areas ... many of these counties are extremely large (example: Meade county, SD, covers 3500 square miles). Potential users in these counties may be dozens of miles away from black-footed ferrets, and should not be arbitrarily excluded from using the product.

The available research shows that b-f ferrets travel less than 5 miles from their home territory (EPA's RED for Strychnine, page 8, and Wildlife Notebook No. 8 by the UT Div. of Wildlife Resources).

This travel distance is also a reason to include application sites bordering one of the listed counties. Our discussions with US FWS personnel raised this concern, and thus we included the language in order to address that concern. On the label we will submit, we will change the language to "application sites adjacent to these counties." Of course, we are happy to consider alternative language that EPA feels is more descriptive or enforceable.

This text includes a reference to "re-introduction" in order to communicate the reason for these restrictions to the potential user. Our work over the past 7 years has shown that many landowners believe that b-f ferrets are extinct in these areas, and are not aware of the re-introductions made by US FWS. EPA's label improvement programs as repeatedly emphasized that users are much more likely to follow instructions and restrictions when they fully understand the reasons for them.

We understand that there are other concerns apart from the b-f ferrets. We believe that the other three mitigation measures proposed will reduce

the availability of carcasses and/or intoxicated animals on the surface of the ground, and thus will decrease the potential exposure to birds and non-target mammals, including ferrets and other threatened or endangered species.

I will be preparing our submission on Monday morning, and am happy to accept your further comments!

Thanks
Tom Schmit
Liphatech, Inc.

-----Original Message-----
From: Laws.Meredith@epamail.epa.gov
[mailto:Laws.Meredith@epamail.epa.gov]
Sent: Thursday, June 17, 2010 3:30 PM

To: Thomas Schmit
Cc: Hebert.John@epamail.epa.gov; Rossi.Lois@epamail.epa.gov; Carl Tanner
Subject: RE: proposed amendment to Rozol Prairie Dog Bait label

Tom - I've looked at the label. Why wouldn't you simply off-label the 19 counties, ie."Do Not Use in Logan County, Kansas; Colfax County, New Mexico...etc.

The proposed text has unenforceable language ("sites bordering these counties" is undefined). The reference to "re-introduction" of the black footed ferret clutters the paragraph. Simply saying "don't use in..." is much cleaner.

Please note that the Black footed ferret is not necessarily the only listed species that could be affected by the use of Rozol. Off-labeling these counties may not alleviate all concerns.

- Meredith

From: "Thomas Schmit" <SchmitT@liphatech.com>

To: Meredith Laws/DC/USEPA/US@EPA

Cc: Lois Rossi/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA, "Carl Tanner" <TannerC@liphatech.com>

Date: 06/16/2010 12:08 PM

Subject: RE: proposed amendment to Rozol Prairie Dog Bait label

Hello Meredith -

After further discussions, we believe that additional mitigation measures are needed on our label for Rozol Prairie Dog Bait (EPA Reg. No. 7173-286). I have attached a draft label so that you can clearly see the mitigation language that we would propose (printed in red text on the attached label).
We do NOT propose any changes concerning application method; all four proposed changes are clearly mitigation measures:

- Left panel, under Endangered Species Considerations: Adds specific site information and buffer requirements for protection

of black-footed ferrets.

- Right panel, under "Treatment period": This changes the language of the currently-approved label "or before spring green-up of prairie grasses, whichever occurs later," to impose a firm, enforceable date for the end of the treatment season.

- Right panel, under "Follow-up": This change requires much more frequent carcass searches (every other day) on the treated area, replacing the currently-approved label language requiring only 2 carcass searches following application.

- Right panel, also under "Follow-up": This change is needed to allow for proper carcass disposal in northern states where frozen ground prevents users from complying with the currently-approved label's requirement to bury carcasses.

Through our contacts with Lois Rossi, we have been told that EPA may already have language for black-footed ferrets. If so, please provide us with that required language.

I will be calling you soon to review this.
Thank you for your consideration!

Tom Schmit
Liphatech, Inc.

-----Original Message-----
From: Laws.Meredith@epamail.epa.gov
[mailto:Laws.Meredith@epamail.epa.gov]
Sent: Friday, June 11, 2010 3:22 PM
To: Thomas Schmit
Cc: Rossi.Lois@epamail.epa.gov; Hebert.John@epamail.epa.gov
Subject: proposed amendment

Tom:

It is my understanding that there is some confusion about whether we would act on a fast track amendment for Rozol. As you and I discussed last Thursday, if LiphaTech submits an amendment that prohibits use in counties where the Black Footed Ferret is present - and no other label changes are included in that amendment - we would expect to be able to act on it within the 90-day fast track review time.

- Meredith

Meredith Laws, Chief
Insecticide-Rodenticide Branch
Registration Division
Office of Pesticide Programs
(703) 308-7038
http://www.epa.gov/pesticides

[attachment "7173-286 (061610) draft.pdf" deleted by Meredith Laws/DC/USEPA/US]

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

CAUTION: Harmful if swallowed or absorbed through the skin because it may reduce the clotting ability of blood and cause bleeding. Keep away from children, domestic animals and pets. Do not get in eyes on skin or on clothing. All handlers (including applicators) must wear shoes plus socks, and gloves. Any person who retrieves carcasses or unused bait following application of this product must wear gloves.

USER SAFETY REQUIREMENTS: Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands thoroughly after applying bait and before eating, drinking , chewing gum, using tobacco or using the toilet and change into clean clothing.

FIRST AID: Have label when obtaining treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor.

If on skin: Take off contaminated clothing. Rinse skin with plenty of cool water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

TREATMENT FOR PET POISONING: If animal eats bait, call veterinarian at once.

NOTE TO PHYSICIAN OR VETERINARIAN: Anticoagulant Chlorophacinone: If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. **For humans or dogs** that have ingested this product and/or have obvious poisoning symptoms (bleeding or prolonged prothrombin times), give Vitamin K_1 intramuscularly or orally.

ENVIRONMENTAL HAZARDS: This product is toxic to fish and wildlife. Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten this bait. Do not apply directly to water, or to areas where surface water is present. Do not contaminate water by cleaning of equipment or disposal of wastes. Runoff also may be hazardous to aquatic organisms in water adjacent to treated areas.

ENDANGERED SPECIES CONSIDERATIONS: It is a Federal offense to use any pesticide in a manner that results in the death of an endangered species. Use of this product may pose a hazard to endangered or threatened species. Applicators may obtain information regarding the occurrence of endangered species and use limitations for this product by calling EPA's "Endangered Species Hotline" at 1-800-447-3813 to obtain an "Interim Measures" pamphlet for your county. You may also consult your local agricultural extension office or state pesticide lead agency to determine if there are any requirements for use of this product. Endangered black-footed ferrets have been re-introduced into the following counties: Kansas: Logan county. New Mexico: Colfax county. Montana: Big Horn, Blaine, Phillips, Rosebud counties. South Dakota: Custer, Dewey, Fall River, Corson, Jackson, Lyman, Meade, Mellette, Pennington, Shannon, Stanley, Todd and Ziebach counties. Before applying this product in these counties, or to sites bordering these counties, you must contact the endangered species specialist at the nearest U.S. Fish and Wildlife Service office to determine the location of black-footed ferret populations. Do not apply this product within five (5) miles of any known or suspected black-footed ferret populations.

RESTRICTED USE PESTICIDE

DUE TO HAZARD TO NONTARGET ORGANISMS

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification.

Active Ingredient: chlorophacinone	0.005%
Inert Ingredients	99.995%
Total	100.000%

EPA Reg. No. 7173-286 EPA Est. No. 7173-WI-1

KEEP OUT OF REACH OF CHILDREN

CAUTION: See side panel for additional precautionary statements.

LIPHATECH®

Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209
(414) 351-1476

NET WEIGHT:

NOT APPROVED

JPA

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL and follow all use directions and precautions. Only use for sites, pests, and application methods specified on this label.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Dispose of product container, unused, spoiled and unconsumed bait as specified on this label.

Use restrictions: This product may only be used as follows:

1. Sites/Pests: Black-Tailed Prairie Dogs *(Cynomys ludovicianus)* on rangeland and adjacent noncrop areas.

2. States: Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas and Wyoming.

3. Application Method: Hand application of bait, at least 6 inches down prairie dog burrows. This product may only be used in underground applications. **Do not apply bait on or above ground level. Treat only active burrows.**

4. Treatment Period: Apply between October 1 and March 15 of the following year, when animals will most readily take the grain bait.

5. Non-Applicators: Do not allow children, pets, domestic animals or persons not involved in the application to be in the area where the product is being applied.

6. Grazing Restriction: Do not allow livestock to graze in treated areas for 14 days after treatment and when no bait is found above ground.

Site Assessment: Before applying this product, identify active prairie dog burrows by visual observation. The openings of active burrows will generally be free of leaves, seeds, other debris or spider webs, and will show freshly turned earth, and have prairie dog feces nearby.

Application: Apply 1/4 cup (53 grams or nearly 2 ounces) of bait at least 6 inches down active prairie dog burrows. **Make sure no bait is left on the soil surface at the time of application.** Applicator must retrieve and dispose of any bait that is spilled above ground or placed less than 6 inches down the burrow entrance.

Follow-up: Prairie dogs that have eaten this bait will begin to die off in 4 to 5 days after they eat a lethal amount. The applicator must return to the site within 4 days after bait application, and at 1 to 2 day intervals, to collect and properly dispose of any bait or dead or dying prairie dogs found on the surface. All carcasses found above ground must be collected and disposed of properly. Continue to collect and dispose of dead or dying prairie dogs and search for nontarget animals for at least two weeks, but longer if carcasses are still being found at that time. Carcass collections should occur in late afternoon, near sundown, to reduce the potential of nocturnal animals finding carcasses and dying animals. Bury carcasses on site in holes dug at least 18 inches deep or in inactive burrows (no longer being used by prairie dogs or other species) to avoid non-target animal scavenging. Burial includes covering and packing the hole or burrow with soil. If burial is not practical (due to frozen ground, etc) collected carcasses should be wrapped in several layers of newspaper and disposed of in trash collection containers that have tight fitting lids which will prevent scavengers from accessing the carcasses. If allowed by state and local authorities, carcasses may burned.

Reapplication: If prairie dog activity persists several weeks or months after the bait was applied, a second application may be made, by treating burrows in the same manner, time period and procedure as the first application. Follow all application, site assessment and follow-up directions and use restrictions as found above.

WARRANTY: To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material when such use and/or handling is contrary to label instructions. (061610)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. **Pesticide Storage:** Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals. **Pesticide Disposal:** Wastes resulting from the use of this product may be placed in trash or delivered to an approved waste disposal facility. **Container Handling:** Nonrefillable container. Do not reuse or refill this container. Dispose of empty container by placing in trash, at an approved waste disposal facility or by incineration or, if allowed by state and local authorities, by burning. If burned stay out of smoke.

Fee for Service {876962J~

This package includes the following

- ○ New Registration
- ◉ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 7

Receipt No. S-	876962
EPA File Symbol/Reg. No.	7173-286
Pin-Punch Date:	6/22/2010

☒ This item is NOT subject to FFS action.

Action Code:

Requested: ____

Granted: ____

Amount Due: $ _____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: Hope Johnson Date: 6/24/10

Remarks: If EFED review is required - send for recoding

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 24, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

THOMAS SCHMIT
LIPHATECH, INC.
3600 W. ELM STREET
MILWAUKEE, WI 53209

PRODUCT NAME: ROZOL PRAIRIE DOG BAIT
COMPANY NAME: LIPHATECH, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 7173-286
EPA RECEIPT DATE: 06/22/10

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 7, at (703) 308-6249.

Sincerely,

P. K. Moore
Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

CAUTION: Harmful if swallowed or absorbed through the skin because it may reduce the clotting ability of blood and cause bleeding. Keep away from children, domestic animals and pets. Do not get in eyes on skin or on clothing. All handlers (including applicators) must wear shoes plus socks, and gloves. Any person who retrieves carcasses or unused bait following application of this product must wear gloves.

USER SAFETY REQUIREMENTS: Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands thoroughly after applying bait and before eating, drinking , chewing gum, using tobacco or using the toilet and change into clean clothing.

FIRST AID: Have label when obtaining treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor.

If on skin: Take off contaminated clothing. Rinse skin with plenty of cool water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

TREATMENT FOR PET POISONING: If animal eats bait, call veterinarian at once.

NOTE TO PHYSICIAN OR VETERINARIAN: Anticoagulant Chlorophacinone: If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. **For humans or dogs** that have ingested this product and/or have obvious poisoning symptoms (bleeding or prolonged prothrombin times), give Vitamin K_1 intramuscularly or orally.

ENVIRONMENTAL HAZARDS: This product is toxic to fish and wildlife. Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten this bait. Do not apply directly to water, or to areas where surface water is present. Do not contaminate water by cleaning of equipment or disposal of wastes. Runoff also may be hazardous to aquatic organisms in water adjacent to treated areas.

ENDANGERED SPECIES CONSIDERATIONS: It is a Federal offense to use any pesticide in a manner that results in the death of an endangered species. Use of this product may pose a hazard to endangered or threatened species. Applicators may obtain information regarding the occurrence of endangered species and use limitations for this product by calling EPA's "Endangered Species Hotline" at 1-800-447-3813 to obtain an "Interim Measures" pamphlet for your county. You may also consult your local agricultural extension office or state pesticide lead agency to determine if there are any requirements for use of this product. Endangered black-footed ferrets have been re-introduced into the following counties: Kansas: Logan county. New Mexico: Colfax county. Montana: Big Horn, Blaine, Phillips, Rosebud counties. South Dakota: Custer, Dewey, Fall River, Corson, Jackson, Lyman, Meade, Mellette, Pennington, Shannon, Stanley, Todd and Ziebach counties. Before applying this product in these counties, or to sites adjacent to these counties, you must contact the endangered species specialist at the nearest U.S. Fish and Wildlife Service office to determine the location of black-footed ferret populations. Do not apply this product within five (5) miles of any known or suspected black-footed ferret populations.

RESTRICTED USE PESTICIDE

DUE TO HAZARD TO NONTARGET ORGANISMS

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification.

Active Ingredient: chlorophacinone	0.005%
Inert Ingredients	99.995%
Total	100.000%

EPA Reg. No. 7173-286 EPA Est. No. 7173-WI-1

KEEP OUT OF REACH OF CHILDREN

CAUTION: See side panel for additional precautionary statements.

LIPHATECH®

Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209
(414) 351-1476

NET WEIGHT:

Not stamped; superseded by 8/20/10 label (sent via Email) —

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL and follow all use directions and precautions. Only use for sites, pests, and application methods specified on this label.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Dispose of product container, unused, spoiled and unconsumed bait as specified on this label.

Use restrictions: This product may only be used as follows:

1. **Sites/Pests:** Black-Tailed Prairie Dogs *(Cynomys ludovicianus)* on rangeland and adjacent noncrop areas.
2. **States:** Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas and Wyoming.
3. **Application Method:** Hand application of bait, at least 6 inches down prairie dog burrows. This product may only be used in underground applications. **Do not apply bait on or above ground level. Treat only active burrows.**
4. **Treatment Period:** Apply between October 1 and March 15 of the following year, when animals will most readily take the grain bait.
5. **Non-Applicators:** Do not allow children, pets, domestic animals or persons not involved in the application to be in the area where the product is being applied.
6. **Grazing Restriction:** Do not allow livestock to graze in treated areas for 14 days after treatment and when no bait is found above ground.

Site Assessment: Before applying this product, identify active prairie dog burrows by visual observation. The openings of active burrows will generally be free of leaves, seeds, other debris or spider webs, and will show freshly turned earth, and have prairie dog feces nearby.

Application: Apply 1/4 cup (53 grams or nearly 2 ounces) of bait at least 6 inches down active prairie dog burrows. **Make sure no bait is left on the soil surface at the time of application.** Applicator must retrieve and dispose of any bait that is spilled above ground or placed less than 6 inches down the burrow entrance.

Follow-up: Prairie dogs that have eaten this bait will begin to die off in 4 to 5 days after they eat a lethal amount. The applicator must return to the site within 4 days after bait application, and at 1 to 2 day intervals, to collect and properly dispose of any bait or dead or dying prairie dogs found on the surface. All carcasses found above ground must be collected and disposed of properly. Continue to collect and dispose of dead or dying prairie dogs and search for nontarget animals for at least two weeks, but longer if carcasses are still being found at that time. Carcass collections should occur in late afternoon, near sundown, to reduce the potential of nocturnal animals finding carcasses and dying animals. Bury carcasses on site in holes dug at least 18 inches deep or in inactive burrows (no longer being used by prairie dogs or other species) to avoid non-target animal scavenging. Burial includes covering and packing the hole or burrow with soil. If burial is not practical (due to frozen ground, etc) collected carcasses should be wrapped in several layers of newspaper and disposed of in trash collection containers that have tight fitting lids which will prevent scavengers from accessing the carcasses. If allowed by state and local authorities, carcasses may burned.

Reapplication: If prairie dog activity persists several weeks or months after the bait was applied, a second application may be made, by treating burrows in the same manner, time period and procedure as the first application. Follow all application, site assessment and follow-up directions and use restrictions as found above.

WARRANTY: To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material when such use and/or handling is contrary to label instructions. (061610)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. **Pesticide Storage:** Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals. **Pesticide Disposal:** Wastes resulting from the use of this product may be placed in trash or delivered to an approved waste disposal facility. **Container Handling:** Nonrefillable container. Do not reuse or refill this container. Dispose of empty container by placing in trash, at an approved waste disposal facility or by incineration or, if allowed by state and local authorities, by burning. If burned stay out of smoke.

LIPHATECH

3600 WEST ELM STREET
MILWAUKEE, WI 53209
Tel: 414/351 1476 800/351 1476
Fax: 414/247 8166

Document Processing Desk
EPA Office of Pesticide Programs (7504P)
One Potomac Yard, Room S4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Mr. Kable Davis, Insecticide/Rodenticide Branch, Registration Division

June 21, 2010

Re: Label amendment submission for
"Rozol Prairie Dog Bait" EPA Reg. No. 7173-286

Dear Mr. Davis,

The enclosed amendment application package is submitted in order to change the label of this product. We believe that this action is a fast track amendment that does not fall into any PRIA Fee Category and thus requires no fee.

This amendment is intended to replace the label amendment we submitted last year. Liphatech hereby withdraws the label amendment submitted with by our cover letter dated Jun 23, 2009 (acknowledgement letter from Front End Processing date July 1, 2009).

The label changes are proposed to increase the protection of non-target wildlife, as described below. We do NOT propose any changes concerning application method; all four proposed changes are clearly mitigation measures. I have enclosed a copy of this label with the proposed changes shown in red, as follows:

1. Left panel, under Endangered Species Considerations: Our proposed change adds a specific requirement to consult US FSW and buffer requirements for protection of black-footed ferrets in specific counties. We do not believe it is necessary to prohibit use in entire counties, as black-footed ferrets may be present only in specific areas of these large counties (example: Meade county, SD, covers 3500 square miles). Potential users in these counties may be dozens of miles away from black-footed ferrets, and should not be arbitrarily excluded from using the product. The available research shows that b-f ferrets travel less than 5 miles from their home territory (EPA's RED for Strychnine, page 8, and Wildlife Notebook No. 8 by the UT Div. of Wildlife Resources). This text includes a reference to "re-introduction" in order to communicate the reason for these restrictions to the potential user. Our work over the past 7 years has shown that many landowners believe that ferrets are extinct in these areas, and are not aware of the re-introductions made by US FWS. EPA's label improvement programs as repeatedly emphasized that users are much more likely to follow instructions and restrictions when they fully understand the reasons for them.

2. Right panel, under "Treatment period": This changes the language of the currently-approved label "or before spring green-up of prairie grasses, whichever occurs later," to impose a firm, enforceable date for the end of the treatment season.

3. Right panel, under "Follow-up": This change requires more frequent carcass searches (every other day) on the treated area, replacing the currently-approved label language that requires only 2 carcass searches following application.

4. Right panel, also under "Follow-up": This change is needed to allow for proper carcass disposal in northern states where frozen ground prevents users from complying with the currently-approved label's requirement to bury carcasses.

Both Meredith Laws and Lois Rossi are aware of this amendment submission, and may have additional information for you. Thank you for your attention to this matter. Please contact me directly if there is any problem or question concerning this submission.

Sincerely,

Thomas Schmit
Manager of Regulatory Affairs

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[X] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
7173-286	John HebertKable Davis	[X] None [ ] Restricted
4. Company/Product (Name) Rozol Prairie Dog Bait	PM# Insecticide/Rodenticide Branch	

5. Name and Address of Applicant *(Include ZIP Code)*

Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209

[ ] *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

The enclosed amendment application is submitted in order to make label changes that will increase the protection of non-target wildlife, as described on our cover letter dated JUne 21, 2010. We believe that this action does not fall into any PRIA category, and requires no fee. Please contact Thomas Schmit at 414-410-7230, or schmitt@liphatech.com with any questions or concerns.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Reteil Container	5. Location of Label Directions
[X] Label [ ] Container	1.06 ounces (30 grams)	[✓] On label

6. Manner in Which Lebel is Affixed to Product: [X] Lithograph [X] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas Schmit	Manager of Regulatory Affairs	(414) 410-7230

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingilly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	
Thomas Schmit	Manager of Regulatory Affairs	
4. Typed Name: Thomas Schmit	5. Date: June 21, 2010	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

LIPHATECH

3600 WEST ELM STREET
MILWAUKEE, WI 53209
Tel: 414/351 1476 800/351 1476
Fax: 414/247 8166

Document Processing Desk
EPA Office of Pesticide Programs (7504C)
Ariel Rios Building
1200 Pennsylvania Ave. N.W.
Washington, DC 20460

Attn: Mr. John Hebert

18 December, 2009

Re: 90 day response to EPA letter dated October 29, 2009, concerning Rozol Prairie Dog Bait, EPA Reg. No. 7173-286

Dear Mr. Hebert,

This letter is Liphatech's commitment to conduct an avian reproduction study pursuant to OPP Guideline 850.2300 and submit the study to EPA within 3 years of EPA's letter.

Please contact me directly at (414) 410-7230 if you have questions concerning this submission.

Sincerely,

Thomas Schmit
Manager of Regulatory Affairs

Modified Conditions-continued

A. **within 30 days** of this letter, submits requests for voluntary cancellation of all SLN registrations for prairie dog uses to the affected states and to EPA;

B. **within 90 Days** of this letter, commits to conduct an Avian Reproduction Study pursuant to guideline 850.2300 within three (3) years of this letter;

C. **within three (3) years** of this letter, submits an appropriate Avian Reproduction Study;

D. submits a revised Confidential Statement of Formula (CSF) for this product, completely filled out, including all the ingredients; and

E. submits one (1) copy of final printed labeling, with the changes specified in our original May 13, 2009, Notice of Registration.

Non-Compliance

Within 90 days of this letter, if you do not intend to meet the above conditions for continued registration, we ask that you submit a request for voluntary cancellation of both this product and all your Special Local Need (SLN) registrations for prairie dog uses.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

Acceptance of Conditions

Your release for shipment of the product constitutes acceptance of these modified conditions.

Additional Reviews

EPA has completed additional reviews of two studies supporting this registration.

We enclose a review of the Hazard Component of your Field Study (MRID No. 473336-02), which concluded that "This study is classified as invalid for addressing the secondary exposure data gap."

We also enclose a review of a study (MRID No. 473336-03) on chlorophacinone residues in prairie whole body and liver tissues, which was classified as "supplemental."

Public Comment

In response to the World Wildlife Fund's petition to suspend this registration and to cancel certain application sites, the Agency published a Notice in the Federal Register on October 7, 2009, requesting public comment for a period of 30 days on this petition, which the Agency expects to extend for an additional 31 days, until December 7, 2009.

Public Comment-continued

As additional background to this Federal Register Notice, EPA is providing copies of the original Notice of Registration, product reviews, and recent letters from the Fish and Wildlife Service (FWS) and other interested parties expressing similar concerns about this registration in a public docket (EPA-HQ-OPP-2009-0684).

Further Evaluation of Registration

After the end of the 61 day comment period on the World Wildlife Fund petition, the Agency will consider the comments and may take additional regulatory actions, in addition to the modified conditions of registration outlined in this letter. Among the issues EPA may consider is whether the addition of further conditions of registration, such as the following, is necessary to ensure that this product will not generally cause unreasonable adverse effects on the environment:

A. Commitment to conduct, and the submission of, the Avian Reproduction Study on two species, with EPA-approved protocols.
B. Commitment to conduct, and the submission of, the Avian Reproduction Study sooner than three (3) years from the date of this letter.
C. Commitment to conduct a valid hazard study to measure the secondary exposure of this use to nontarget organisms, with an EPA-approved protocol;
D. Advance submission of proposed protocols for the Avian Reproduction Study and the secondary exposure study.
E. Additional label changes, such as additional use restrictions or follow-up requirements.

Questions

If you have questions about this letter, please contact me at 703-305-5407 (phone); 703-305-6596 (fax); or peacock.dan@epa.gov (E-Mail).

Sincerely,

DBP

Daniel B. Peacock, Biologist
Insecticide-Rodenticide Branch
Registration Division (7504C)

Enclosures

1. EPA Review of 473232-01, Avian Reproduction Study for Chlorophacinone
2. Code of Federal Regulations (40 CFR 158.630)
3. Review of Hazard Component of Field Study (MRID No. 473336-02) and chlorophacinone whole body/liver tissue study (MRID No. 473336-03)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM **DATE: 2 October 2009**

SUBJECT: **Reply to Formal Response Concerning Use of Two Avian Reproduction Studies to Fulfill Notice of Registration Requirement for Chlorophacinone**

FROM: **Andrew Shelby, Physical Scientist**
Environmental Fate and Effects Division, Environmental Risk Branch II

THRU: **Tom Bailey, Branch Chief** for Tom Bailey 10/2/09
Environmental Fate and Effects Division, Environmental Risk Branch II

TO: **Dan Peacock, Biologist**
Registration Division, Insecticide Rodenticide Branch

The Agency has reviewed the request to waive the avian reproduction study data requirement for chlorophacinone submitted by Liphatech Inc. The Agency is unable to accept the two studies suggested to fulfill this requirement for the reasons outlined below.

The first suggested study was "Subacute and Subchronic Toxicity of Chlorophacinone in Japanese Quail" (MRID 47323201) published in the Archives of Experimental Veterinary Medicine. While we reserve the discretion to include open literature studies in our risk assessments, we cannot accept this open literature study as a replacement for the avian reproduction study requirement. Over 90% of the avian reproduction endpoints are not measured. Though total mass of eggs and eggs per hen are measured, embryo survival endpoints, hatching endpoints and hatchling survival endpoints are not determined. Finally, raw data is not included disallowing independent validation of the results.

The second suggested study was "Avian Reproduction Study with Difenacoum in the Japanese Quail" (MRID 46799101). Chlorophacinone and difenacoum are very distinct chemicals. Treating difenacoum as a surrogate chemical is inappropriate and cannot be justified without an acceptable bridging strategy. Disparate chemical structures preclude the acceptance of this study for fulfilling the avian reproduction data gap for chlorophacinone.

Please refer to OPPTS Harmonized Test Guideline 850.2300 for a more thorough explanation as to how to fulfill this data requirement. The Agency welcomes constructive comments and suggestions through the registration process. However, your formal response does not satisfy conditions of our May 13, 2009 Notice of Registration to your company. For further consideration of this new use registration of Rozol, acceptable avian reproduction studies on two species must be submitted in accordance with registration timelines.

ENTS—Continued

Indoor	Test substance	Test Note No.
NR	TGAI	1, 4
NR	TGAI	5
NR	TGAI	1, 4
NR	TEP	6, 7
CR	TGAI, TEP	1, 2, 6, 9, 26
CR	TGAI, TEP	1, 2, 9, 10, 26
NR	TGAI, TEP	1, 9, 11, 12, 26
NR	TGAI	1, 10, 12
NR	TGAI	12, 14, 15
NR	TGAI	1, 12, 13
NR	TGAI	12, 15, 16
NR	TGAI	17, 18
NR	TGAI, PAI, degradate	19
IR	TEP	7, 20
R	TGAI	21
R	TGAI	21, 23

TERRESTRIAL AND AQUATIC NONTARGET ORGANISM DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry	Residential Outdoor	Greenhouse	Indoor		
	Whole sediment: chronic invertebrates freshwater and marine	CR	CR	CR	CR	NR	NR	TGAI	22, 23
Insect Pollinator Testing									
850.3020	Honeybee acute contact toxicity	R	CR	R	R	NR	NR	TGAI	1
850.3030	Honey bee toxicity of residues on foliage	CR	CR	CR	CR	NR	NR	TEP	24
850.3040	Field testing for pollinators	CR	CR	CR	CR	NR	NR	TEP	25

(e) *Test notes.* The following test notes apply to terrestrial and aquatic nontarget organisms data requirements in the table to paragraph (d) of this section:

1. Data using the TGAI are required to support all outdoor end-use product uses including, but not limited to turf. Data are generally not required to support end-use products in the form of a gas, a highly volatile liquid, a highly reactive solid, or a highly corrosive material.

2. For greenhouse and indoor end-use products, data using the TGAI are required to support manufacturing-use products to be reformulated into these same end-use products or to support end-use products when there is no registered manufacturing-use product. Avian acute oral data are not required for liquid formulations for greenhouse and indoor uses. The study is not required if there is no potential for environmental exposure.

3. Data are required on one passerine species and either one waterfowl species or one upland game bird species for terrestrial, aquatic, forestry, and residential outdoor uses. Data are preferred on waterfowl or upland game bird species for indoor and greenhouse uses.

4. Data are required on waterfowl and upland game bird species.

5. Tests are required based on the results of lower tier toxicology studies, such as the acute and subacute testing, intended use pattern, and environmental fate characteristics that indicate potential exposure.

6. Higher tier testing may be required for a specific use pattern when a refined risk assessment indicates a concern based on laboratory toxicity endpoints and refined exposure assessments.

7. Environmental chemistry methods used to generate data associated with this study must include results of a successful confirmatory method trial by an independent laboratory. Test standards and procedures for independent laboratory validation are available as addenda to the guideline for this test requirement.

8. Data are required on one coldwater fish and one warmwater fish for terrestrial, aquatic, forestry, and residential outdoor uses. For indoor and greenhouse uses, testing with only one of either fish species is required.

9. EP or TEP testing is required for any product which meets any of the following conditions:

i. The end-use pesticide will be introduced directly into an aquatic environment (e.g., aquatic herbicides and mosquito larvicides) when used as directed.

ii. The maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment is ≥ one-half the LC_{50} or EC_{50} of the TGAI when the EP is used as directed.

iii. An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms.

10. Data are required on one freshwater aquatic invertebrate species.

11. Data are required on one estuarine/marine mollusk, one estuarine/marine invertebrate and one estuarine/marine fish species.

12. Data are generally not required for outdoor residential uses, other than turf, unless data indicate that pesticide residues from the proposed use(s) can potentially enter waterways.

13. Data are required on one freshwater fish species. If the test species is different from the two species used for the freshwater fish acute toxicity tests, a 96-hour LC_{50} on that species must also be provided.

14. Data are required on one estuarine/marine invertebrate species.

15. Data are required on estuarine/marine species if the product meets any of the following conditions:

i. Intended for direct application to the estuarine or marine environment.

ii. Expected to enter this environment in significant concentrations because of its expected use or mobility patterns.

iii. If the acute LC_{50} or EC_{50} < 1 milligram/liter (mg/l).

iv. If the estimated environmental concentration (EEC) in water is ≥ 0.01 of the acute EC_{50} or LC_{50} or if any of the following conditions exist:

A. Studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected.

B. Physicochemical properties indicate bioaccumulation of the pesticide.

C. The pesticide is persistent in water (e.g., half-life in water > 4 days).

16. Data are required on one estuarine/marine fish species.

17. Data are required on estuarine/marine species if the product is intended for direct application to the estuarine or marine environment, or the product is expected to enter this environment in significant concentrations because of its expected use or mobility patterns.

18. Data are required on freshwater species if the end-use product is intended to be applied directly to water, or is expected to be transported to water from the intended use site, and when any of the following conditions apply:

i. If the estimated environmental concentration (EEC) is ≥ 0.1 of the no-observed-effect level in the fish early-life stage or invertebrate life cycle test;

ii. If studies of other organisms indicate that the reproductive physiology of fish may be affected.

19. Not required when:

i. The octanol/water partition coefficients of the pesticide and its major degradates are < 1,000; or

ii. There are no potential exposures to fish and other nontarget aquatic organisms; or

iii. The hydrolytic half-life is < 5 days at pH 5, 7 and 9.

20. Data are required based on the results of lower tier studies such as acute and chronic aquatic organism testing, intended use pattern, and environmental fate characteristics that indicate significant potential exposure.

21. Data are required if:

i. The half-life of the pesticide in the sediment is ≤ 10 days in either the aerobic soil or aquatic metabolism studies and if any of the following conditions exist:

A. The soil partition coefficient (Kd) is ≥ 50.

B. The log Kow is ≥ 3.

C. The Koc ≥ 1,000.

ii. Registrants must consult with the Agency on appropriate test protocols prior to designing the study.

22. Data are required if:

i. The estimated environmental concentration (EEC) in sediment is > 0.1 of the acute LC_{50}/EC_{50} values and

ii. The half-life of the pesticide in the sediment is > 10 days in either the aerobic soil or aquatic metabolism studies and if any of the following conditions exist:

A. The soil partition coefficient (Kd) is ≥ 50.

B. The log Kow is ≥ 3.

C. The Koc ≥ 1,000.

iii. Registrants must consult with the Agency on appropriate test protocols prior to designing the study.

23. Sediment testing with estuarine/marine test species is required if the product is intended for direct application to the estuarine or marine environment or the product is expected to enter this environment in concentrations which the Agency believes to be significant, either by runoff or erosion, because of its expected use or mobility pattern.

24. Data are required only when the formulation contains one or more active ingredients having an acute LD_{50} of < 11 micrograms per bee as determined in the honey bee acute contact study and the use pattern(s) indicate(s) that honey bees may be exposed to the pesticide.

25. Required if any of the following conditions are met:

i. Data from other sources (Experimental Use Permit program, university research, registrant submittals, etc.) indicate potential adverse effects on colonies, especially effects other than acute mortality (reproductive, behavioral, etc.);

ii. Data from residual toxicity studies indicate extended residual toxicity.

iii. Data derived from studies with terrestrial arthropods other than bees indicate potential chronic, reproductive or behavioral effects.

26. The freshwater fish test species for the TEP testing is the most sensitive of the species tested with the TGAI. Freshwater invertebrate and acute estuarine and marine organisms must also be tested with the EP or TEP using the same species tested with the TGAI.

§ 158.660 Nontarget plant protection data requirements table.

(a) *General.* Sections 158.100 through158.130 describe how to use this table to determine the nontarget plant data requirements for a pa ticide product. Notes that individual test and inclu conditions, qualifications, tions to the designated tes in paragraph (e) of this secti

(b) *Use patterns.* (1) The use pattern includes produc under the general use patt restrial food crop, terrestria and terrestrial nonfood. T use pattern includes only use patterns of aquatic foo aquatic nonfood.

TABLE—NONTAR

Guideline Number	Data Require
Nontarget Area Phytotoxicity - Tier I	
850.4100	Seedling emerge
850.4150	Vegetative vigor
850.4400 850.5400	Aquatic plant gro (algal and aqua cular plant toxic
Nontarget Area Phytotoxicity - Tier II	
850.4100	Seedling emerger
850.4150	Vegetative vigor
850.4400 850.5400	Aquatic plant grow (algal and aquat cular plant toxici
Nontarget Area Phytotoxicity - Tier III	
850.4300	Terrestrial field
850.4450	Aquatic field
Target Area Phytotoxicity	
850.4025	Target area phyto

(e) *Test notes.* The follo notes apply to the table in (d) of this section.

1. Not required for containe treatments such as bait pheromone traps unless adverse ports are received by the Agency.

2. Not required for known phyt

3. Generally not required for gr mulations. May be requested on case basis.

4. Required for known phytotoxi as herbicides, desiccants and defoli

5. Required if a tested terrestr exhibits a 25 percent or greater d

first tier toxicology data. The requirement for additional second and third level toxicology testing will be determined by the Agency based on the results of the first tiered studies.

(1) The required first-tier toxicology studies consist of:

(i) Battery of acute studies.

(ii) A subchronic 90–day dermal study or a subchronic 90–day inhalation study.

(iii) An acute and subchronic neurotoxicity screening battery in the rat.

(iv) Prenatal developmental toxicity studies in both the rat and rabbit.

(v) Reproduction and fertility studies in rats.

(vi) Battery of mutagenicity studies.

(vii) Immunotoxicity study.

(2) The conditionally required second-tier studies include:

(i) Subchronic 90–day feeding studies in both the rodent and nonrodent.

(ii) Dermal penetration study.

(3) The conditionally required third-tier studies include:

(i) Chronic feeding studies in the rodent.

(ii) Carcinogenicity.

(iii) Metabolism study.

(iv) Additional mutagenicity testing.

Subpart G— Ecological Effects

§ 158.630 Terrestrial and aquatic nontarget organisms data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget data requirements for a particular pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop and aquatic nonfood use patterns. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products classified under the general use patterns of indoor food and indoor nonfood use.

(2) Data are also required for the general use patterns of forestry and residential outdoor use.

(3) In general, for all outdoor end-uses, including turf, the following studies are required: Two avian oral LD_{50}, two avian dietary LC_{50}, two avian reproduction studies, two freshwater fish LC_{50}, one freshwater invertebrate EC_{50}, one honeybee acute contact LD_{50}, one freshwater fish early-life stage, one freshwater invertebrate life cycle, and three estuarine acute LC_{50}/EC_{50} studies — fish, mollusk and invertebrate. All other outdoor residential uses, *i.e.*, gardens and ornamental will not usually require the freshwater fish early-life stage, the freshwater invertebrate life-cycle, and the acute estuarine tests.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; TGAI=Technical grade of the active ingredient; TEP=Typical end-use product; PAI=Pure active ingredient; EP=end-use product. Commas between the test substances (*i.e.*, TGAI, TEP) indicate that data may be required on the TGAI or the TEP depending on the conditions set forth in the test note.

(d) *Table.* The following table shows the data requirements for nontarget terrestrial and aquatic organism. The table notes are shown in paragraph (e) of this section.

TERRESTRIAL AND AQUATIC NONTARGET ORGANISM DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry	Residential Outdoor	Greenhouse	Indoor		
Avian and Mammalian Testing									
850.2100	Avian oral toxicity	R	R	R	R	CR	CR	TGAI	1, 2, 3

TERRESTRIAL AND AQUATIC NONTARGET ORGANISM DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry	Residential Outdoor	Greenhouse	Indoor		
850.2200	Avian dietary toxicity	R	R	R	R	NR	NR	TGAI	1, 4
850.2400	Wild mammal toxicity	CR	CR	CR	CR	NR	NR	TGAI	5
850.2300	Avian reproduction	R	R	R	R	NR	NR	TGAI	1, 4
850.2500	Simulated or actual field testing	CR	CR	CR	CR	NR	NR	TEP	6, 7
Aquatic Organisms Testing									
850.1075	Freshwater fish toxicity	R	R	R	R	CR	CR	TGAI, TEP	1, 2, 8, 9, 26
850.1010	Acute toxicity freshwater invertebrates	R	R	R	R	CR	CR	TGAI, TEP	1, 2, 9, 10, 26
850.1025 850.1035 850.1045 850.1055 850.1075	Acute toxicity estuarine and marine organisms	R	R	R	R	NR	NR	TGAI, TEP	1, 9, 11, 12, 28
850.1300	Aquatic invertebrate life cycle (freshwater)	R	R	R	R	NR	NR	TGAI	1, 10, 12
850.1350	Aquatic invertebrate life cycle (saltwater)	CR	CR	CR	CR	NR	NR	TGAI	12, 14, 15
850.1400	Fish early-life stage (freshwater)	R	R	R	R	NR	NR	TGAI	1, 12, 13
850.1400	Fish early-life stage (saltwater)	CR	CR	CR	CR	NR	NR	TGAI	12, 15, 16
850.1500	Fish life cycle	CR	CR	CR	CR	NR	NR	TGAI	17, 18
850.1710 850.1730 850.1850	Aquatic organisms bioavailability, biomagnification, toxicity	CR	CR	CR	CR	NR	NR	TGAI, PAI, degradate	19
850.1950	Simulated or actual field testing for aquatic organisms	CR	CR	CR	CR	NR	NR	TEP	7, 20
Sediment Testing									
850.1735	Whole sediment: acute freshwater invertebrates	CR	CR	CR	CR	NR	NR	TGAI	21
850.1740	Whole sediment: acute marine invertebrates	CR	CR	CR	CR	NR	NR	TGAI	21, 23

TERRESTRIAL AND AQUATIC I

Guideline Number	Data Requirement	Ter tri
	Whole sediment: chronic invertebrates freshwater and marine	CR
Insect Pollinator Testing		
850.3020	Honeybee acute contact toxicity	R
850.3030	Honey bee toxicity of residues on foliage	CR
850.3040	Field testing for pollinators	CR

(e) *Test notes.* The foll notes apply to terrestrial a nontarget organisms dat ments in the table to parag this section:

1. Data using the TGAI are req port all outdoor end-use product ing, but not limited to turf. D erally not required to support e ucts in the form of a gas, a hi liquid, a highly reactive solid, corrosive material.

2. For greenhouse and indoor ucts, data using the TGAI are support manufacturing-use prod formulated into these same end or to support end-use products no registered manufacturing- Avian acute oral data are not liquid formulations for greenh door uses. The study is not req is no potential for environmenta

3. Data are required on one cies and either one waterfowl a upland game bird species fo aquatic, forestry, and reside uses. Data are preferred on wat land game bird species for indo house uses.

4. Data are required on wate land game bird species.

5. Tests are required based on lower tier toxicology studies, acute and subacute testing, int tern, and environmental fate d that indicate potential exposur

6. Higher tier testing may be specific use pattern when a re sessment indicates a concern oratory toxicity endpoints and sure assessments.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DP: 350010

MEMORANDUM

Sept 3, 2009

SUBJECT: Chlorophacinone (067707): Non-target exposure review of "Field Efficacy and Hazards of Rozol Bait for Controlling Black-Tailed Prairie Dogs (*Cynomys ludovicianus*)"

FROM: Andrew Shelby, MSES, MPA
Environmental Fate and Effects Division/ERB2 (MC 7507P)

SECONDARY REVIEW: Jean Holmes, DVM, MPH
Environmental Fate and Effects Division/ERB2
Edward Odenkirchen, Ph. D.
Environmental Fate and Effects Division/ERB1

THRU: Tom Bailey, Branch Chief
Environmental Fate and Effects Division/ERB2 (MC 7507P)

TO: Dan Peacock
Registration Division/IRB (MC 7505P)

Attached is EFED's review of the hazard components for two studies: "Field Efficacy and Hazards of Rozol Bait for Controlling Black-Tailed Prairie Dogs (*Cynomys ludovicianus*)" and "Determination of Chlorophacinone Residues in Prairie Dog Whole Body and Liver Tissues". Registration Division has reviewed the efficacy component of these studies. The major objectives of the studies were to verify efficacy of Rozol Prairie Dog Bait (chlorophacinone 0.005% a.i.) when used for black-tailed prairie dogs and determine chlorophacinone residue concentrations in the resulting carcasses. The studies provide some insight into non-target primary exposure by assessing amount of bait moved to ground surface, however EFED believes a more robust set of carcass and bait searches would be required to reduce the risk of secondary exposure to predators and scavengers of black-tailed prairie dogs. The attached documents review the field hazard study and residue analysis from the perspective of characterizing the primary and secondary exposure potential to non-target animals.

EFED concludes that the hazard component of the attached field study provides limited information regarding non-target primary exposure and is totally insufficient for evaluating non-target secondary exposure. Non-target exposure assessment could be improved if: (1) populations of potential non-target exposed animals were assessed prior to initiation of the study; (2) target animal carcasses were monitored and left for scavenging/predation for longer periods of time; (3) a carcass recovery efficiency test was performed; and (4) carcass search areas were expanded to include ranges of all potentially exposed non-target animals to ensure that study mortalities are not lost due to a small search area. The primary weakness of this study is its attempt to combine field efficacy with non-target exposure. Carcass collection should occur frequently in a field efficacy study to best estimate mortality without the influence of scavenging and predation. In a secondary exposure study, predators and scavengers should be given ample opportunity to feed on carcasses to maximize hazard. This study attempted to combine these methods resulting in unreliable information regarding the hazard component.

EFED further concludes that the attached residue analysis could be improved if carcass handling techniques were explicitly stated and followed. Evidence indicates carcass handling techniques differed between the two residue analyses performed in the study though this cannot be confirmed for lack of explicit methods. The resulting data preclude conservative study results.

Reviewed for non-target exposure, the field efficacy study is classified as "invalid". The residue analysis is classified as "supplemental".

Contact Andrew Shelby at 703-347-0119 if you have any questions.

Responses

Request #1:

Attached is a copy of our review of the study (MRID No. 473232-01) submitted to fulfill the Avian Reproduction Study requirement for chlorophacinone.

Request #2:

EPA received a copy of this study (MRID No. 467991-01) but did not review it independently because the European Union had previously reviewed this study. We have no Data Evaluation Record (DER) for this study. However, we have a copy of a summary and detailed review that the EU conducted on this study and that the Agency received as part of the registration materials to support the registration of difenacoum. If you do not already have a copy of this review, you may request one from EPA.

Request #3:

As indicated in the enclosed review of October 2, 2009, LiphaTech has not satisfied the conditions of registration that LiphaTech commit to conduct, and submit, an Avian Reproduction Study.

The review recommends that "For further consideration of this new use registration of Rozol, acceptable avian reproduction studies on two species must be submitted in accordance with registration timelines." Such a recommendation is consistent with the Agency's most recent guidelines published in the Code of Federal Regulations (40 CFR 158.630), copy enclosed.

Furthermore, as of the date of this letter, EPA has not received a request for voluntary cancellation of all SLN registrations of this product. Submission of such requests is a condition of EPA Reg. No. 7173-286, as stated in EPA's May 13, 2009 Notice.

For the reasons stated above, LiphaTech has not satisfied the conditions of registration as stated in the Notice of Registration for Rozol Prairie Dog Bait, EPA Reg. No. 7173-286, dated May 13, 2009.

Modified Conditions

As a result of these new reviews, we believe modification of the terms and conditions of registration are necessary as follows:

This product may continue to be conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that LiphaTech:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 29, 2009

CERTIFIED MAIL

LiphaTech. Inc.
3600 W. Elm Street
Milwaukee, WI 53209

Attention: Mr. Thomas J. Schmit

Subject **Rozol Prairie Dog Bait**
EPA Reg. No. 7173-286
LiphaTech's July 22, 2009 Response to Conditions of Registration

Purpose In its e-mail of July 22, 2009, LiphaTech responded to the conditions of registration for Rozol Prairie Dog Bait, set forth by EPA in its May 13, 2009 Notice of Registration. The purpose of this letter is to set forth EPA's reply to LiphaTech, provide the modified conditions of registration for this product, and describe additional EPA activity relating to this registration.

Requests In its July 22, 2009, E-Mail, LiphaTech made three requests for:

1. … "a copy of the EPA review document for the chlorophacinone [study] submitted by LiphaTech (MRID number 473232-01);

2. … a copy of the EPA review document for the difenacoum study that we have legal access to (MRID number 467991-01);

3. … a specific determination and written notification from EPA stating that LiphaTech has, or has not, satisfied the conditions of registration as stated in the Notice of Registration for Rozol Prairie Dog Bait, EPA Reg. No. 7173-286, dated May 13, 2009."

Rodenticide: Chlorophacinone (067707)

Study Sponsor: Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209

Performing Laboratory: US Department of Agriculture
National Wildlife Research Center
4101 LaPorte Avenue
Fort Collins, CO 80521

Reviewer: Andrew Shelby, Physical Scientist, ERB2/EFED

Study Classification:

Chlorophacinone (067707): Secondary exposure review of "Determination of Chlorophachinone Residues in Prairie Dog Whole Body and Liver Tissues"

Summary:

This study determines the liver and whole body chlorophacinone residues for prairie dog carcasses collected from "Field Efficacy and Hazards of Rozol Bait for Controlling Black-Tailed Prairie Dogs (*Cynomys ludovicianus*)" (MRID 47333602) and an additional study involving chlorophacinone applications. Laboratory quality control methods in detection of the chemical proved effective but the handling of samples is not discussed and chemical degradation may have occurred as a result. Degradation is suspected because two sets of prairie dog carcasses analyzed, both fed Rozol Bait to mortality, had significantly different chlorophacinone residue levels. The analysis with higher residue concentrations (Table 1) consisted of samples all collected within a three day period. Samples collected for the second analysis (Table 2) were collected over a span of five months. This discrepancy in collection periods could account for differences in the handling of specimens and differences in degradation. Though this may be the cause, the reason for the discrepancy cannot be determined as handling methods are not described.

Table 1: Whole Body and Liver residue analysis for chlorophacinone for prairie dogs fed Rozol to mortality. These carcasses are from a study unassociated with MRID# 473336-02.

Sample Description	NWRC ID	Whole Body Average Corrected Conc. (ppm)	Liver Average Corrected Conc. (ppm)
Found Dead East Pasture 3/30/06	S060503-6	1.72	3.62
Chlorophacinone Treated 3/1-4/06 Bert #1	S060405-14	1.22	3.28
Chlorophacinone Treated 3/1-4/06 Bert #2	S060405-15	1.73	4.28
Chlorophacinone Treated 3/1-4/06 Bert	S060405-16	2.24	6.66

insufficient search ranges, the investigators have significantly underestimated target, non-target primary and non-target secondary exposure.

Hazards to primary and secondarily exposed non-target animals could have been more effectively assessed. Impacts to non-target animal populations can be determined through a variety of techniques including mark-recapture, radio telemetry, catch per unit effort and/or burrow censussing to index population sizes before and after treatment. Carcass monitoring can be implemented using infrared video cameras, a photography system or other conventional methods.

Conclusions:

This study is classified as invalid for addressing the secondary exposure data gap. Carcass searches were too narrow, non-target populations were not monitored, and applications did not maximize risk. Consultation with EFED is suggested for the design of a secondary exposure study.

References:

Marsh, R.E. and W.E. Howard. 1986. Ground squirrel--coyote secondary toxicity studies with chlorophacinone and bromadiolone (an administrative report of laboratory findings). Unpubl. report submitted to EPA by LiphaTech, Inc., Milwaukee, WI.

RESULTS

Population change: Burrow activity declined dramatically in all colonies treated with Rozol. Burrow activity dropped 95% when comparing activity before versus after treatment and a reduction of 84% when comparing untreated versus treated colonies. No observed differences in efficacy were found across the three treatment periods (Fall, Early Winter, and Late Winter) at alpha = 0.05.

Visual counts of prairie dogs declined dramatically in all colonies treated with Rozol. An observed reduction in counts of 94% was found when comparing counts before versus after treatment and a reduction of 96% when comparing untreated versus treated colonies. No effects of environmental conditions on visual counts of prairie dogs were found.

Carcass Availability: During the entire study, only 10 carcasses were found aboveground (9 black-tailed prairie dogs and 1 cottontail) in 5 of the 10 treated colonies. One carcass was found in each of 2 colonies, 2 carcasses were found in 1 colony and 3 carcasses were found in each of 2 colonies. All carcasses were found within the treated areas of the colonies. Carcasses were only found 10 to 25 days (mean = 15.2) after application and most carcasses were found on day 12 of the study. Also observed were 5 impaired prairie dogs in 2 treated colonies at least 10 days after application.

Transects were estimated to search for carcasses with an effective observational width of 200 feet with length ranging from 450 to 2100 feet. The total area is searched every other day for up to 25 days was 143.7 acres. Therefore, the density of carcasses observed above ground due to Rozol intoxication was 0.07 per acre or 1 carcass per 14 acres.

Reviewer's Comments:

The study was designed primarily to determine field efficacy of Rozol Prairie Dog Bait to fulfill product performance data requirements (40 CFR §158.640). Secondary emphasis was placed on determining hazards of bait application to non-target granivores and carcass availability to predators and scavengers. Carcass collection is inappropriate for evaluating secondary exposure hazard because it artificially reduces opportunity for secondary exposure. Rather, it is necessary to monitor carcasses. Carcass monitoring maximizes hazard by allowing predators and scavengers opportunity to feed on poisoned carcasses. This strategy also allows the investigator to determine what type of animal scavenged the carcass. Carcass monitoring can only be carried out effectively with frequent carcass searches. Diurnal and nocturnal predators and scavengers will scavenge carcasses very quickly after they are available. The investigators in this study performed carcass searches and removal every 48 hours when evidence suggests that 12 hour carcass monitoring intervals are more appropriate to account for rapid feeding on carcasses. Though more frequent searches would allow investigators to find more carcasses, many poisoned carcasses would still go unfound. To address this, a carcass search efficiency test should be implemented. Finally, carcass search areas should be large enough to account for non-target animal ranges that are at risk of exposure as determined by the pretreatment non-target animal census. Between too infrequent carcass searches, lacking a carcass search efficiency test and

Bait application: Application of the test substance bait was made by a qualified applicator, who holds the appropriate license for the state where the study plots were located. Application of the test substance bait was made no more than 2 days following the pre-treatment census, and the day of bait application was indicated as Day 0 of the study. Bait application was made to all active prairie dog burrows; that were identified by visual observation of burrow openings; that were generally free of leaves, seeds, other debris or spider webs, and/or showed freshly turned earth, and/or had prairie dog feces nearby. No control substance (placebo bait) was applied to the control plot.

Design for carcass availability on the ground surface:
A methodical carcass search of the complete treated plot and control plot was conducted every other day until termination of the study, to recover all carcasses of both target and non-target animals. These trials are necessary to accurately assess target and non-target animal mortality. Relevant data concerning the time of recovery, species, sex, age (adult vs. juvenile) and condition of the carcass was recorded. The carcass search area extended about 100 feet in all directions beyond the boundaries of the study plots, but was smaller when limited by natural boundaries or property access denial. Carcass searches were conducted during the afternoon hours (weather permitting) to minimize the availability of carcasses to nocturnal predators/scavengers.

All sightings of non-target birds and mammals on or near the study plots were recorded. Any non-target mammal carcasses found on or near the study plots were frozen as soon as possible and submitted to the USDA National Wildlife Research Center (NWRC) for necropsy and analysis.

Design for bait availability on the ground surface:
A methodical bait search of the treated plot was conducted on days 1 through 7 of the study, in order to document whether granules of Rozol Prairie Dog Bait had been moved to the ground surface, or out of the burrows by the normal activity of prairie dogs, predators and scavengers of prairie dogs, or by other wildlife, livestock or domestic animals. The control plot was not searched.

Due to the large number of burrows treated, the bait search was made on 50 burrows that were located along two perpendicular transect lines. Every active burrow where bait was placed was examined for bait visible on the surface of the ground or less than six inches into the burrow. Observations noted any disturbance of the ground, the presence of any predators, scavengers, or other non-target birds or mammals, such as tracks, droppings, scratchings, markings, or any other recognizable sign.

Design for tissue analysis to determine chlorophacinone residues:
All recovered prairie dog carcasses were sent to the USDA NWRC for analysis of chlorophacinone residue levels. Data concerning the location, time of recovery, species, sex, age and condition of the carcass were recorded. Carcasses were frozen as soon as possible, and marked and handled according to SOPs. Further methods will be described from a NWRC report.

Study Sites and Treatments:
The study was conducted in three different areas. Treated sites ranged in size from 2.1 acres to 41.5 acres.

Trial 1 was located in areas of Barton and Safford Counties near the community of Great Bend, Kansas. The elevation at the control site was approximately 1820 feet above sea level, with the soils described as the Kisiwa loam, fairly flooded. Elevation at the Salle test site is approximately 2024 feet and the soil is described as Naron fine loam with 1-3% slopes. The elevation at the Hogan site is 2012 feet and soils are Pratt-Carwile complex with 0-5% slope.

Trial 2 had the control site and two test sites located in Rawlins County, Kansas near the community of Atwood, Kansas. The elevation at the Ryan Cemetery is approximately 3045 feet, the elevation at Ryan SE is approximately 3009 feet and at Ryan Control is 3015 feet. Soils at Ryan SE and Ryan Control are described as Colby silt loam with 10-15% slopes. The other two test sites for Trial 2 were located in the edge of Nebraska in Hitchcock County south of Trenton, Nebraska. The site labeled NE East Lashley is about 3045 feet above sea level with Colby silt loam soils with 9-30% slopes. The NE West Faiman site is about 2966 feet in elevation and the soils are Colby silt loam with 9-30% slopes.

Trial 3 had the control site and all four test sites located near Benkleman, Nebraska. Wiese East is approximately 3060 feet in elevation and has soils described as Sulco loam with slopes 3-6%. Weise West is 3176 feet in elevation and soils are Sulco loam with slopes of 9-30%. The Sowers site is about 3300 feet in elevation with soils described as Colby silt loam with 5-15% slopes. The control site is 3269 feet in elevation with soils described as Valent sand, rolling.

Each plot encompassed a prairie dog colony that contained at least 20 individual animals. To prevent immigration of prairie dogs from outside the treated plot during the trial, the plots selected were physically separated from areas occupied by prairie dogs near roadways, other natural or artificial barriers, or large areas of land not occupied by prairie dogs.

All sites were native rangeland with primarily short grass species and had been grazed by cattle prior to the trial.

Methods:

Efficacy determination:
Census of study plots: A "Visual Count Index" was the direct census method used to estimate prairie dog populations. A "Plugged Burrow Index" was used as a confirmatory (indirect) census method. Both census methods were used before and after the baiting application period, with the Visual Count Index taken before the Plugged Burrow Index, on both the treated plot and the control plot. The pre-treatment census was taken no more than 4 days prior to application of the bait. If inclement weather conditions disrupted normal activity of the prairie dogs, the post-treatment census will be taken as soon as weather conditions stabilized.

The census of the control plot was made within 24 hours before or after the corresponding census was taken on the treated plot.

Rodenticide: Chlorophacinone (067707)

Rozol Prairie Dog Bait

Study Sponsor: Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209

Performing Laboratory: Charles D. Lee
Department of Animal Sciences and Industry
Kansas State University Research and Extension
Room 131 Call Hall
Manhatten, KS 66506

Reviewer: Andrew Shelby, Physical Scientist, ERB2/EFED

Study Classification:

Chlorophacinone (067707): Secondary exposure review of "Field Efficacy and Hazards of Rozol Bait for Controlling Black-Tailed Prairie Dogs (*Cynomys ludovicianus*)"

Data Evaluation Review Summary
The major objective of the study was to determine efficacy of Rozol Prairie Dog Bait (chlorophacinone 0.005% a.i.) when used to control black-tailed prairie dogs. For assessment of the efficacy component, please see the review performed by Registration Division. The study also purports to provide insight into non-target primary exposure by assessing amount of bait moved to ground surface and collecting non-target carcasses. However, neither primary nor secondary non-target risks were adequately assessed due to carcass searches occurring too infrequently and over limited ranges. To adequately assess these risks, the following methods would need to be included: a non-target field census; a carcass recovery efficiency test; expansion of carcass search areas; and carcass monitoring rather than carcass collection.

Study Purpose:
1. Determine the efficacy of Rozol Prairie Dog Bait in controlling black-tailed prairie dogs, when applied in-burrow, at the rate of ¼ cup of bait per active burrow.
2. Determine the (approximate) number of prairie dogs that are available after death to predators/scavengers on the surface of the ground
3. Determine the amount of granules of Rozol Prairie Dog Bait that are moved to the ground surface, out of the burrows, by the normal activity of prairie dogs, predators and scavengers of prairie dogs, or by other wildlife, livestock or domestic animals
4. Provide carcasses of black-tailed prairie dogs collected from treated areas, for tissue analysis to determine whole-body and liver concentrations of chlorophacinone residue
5. Determine if the time of year when application is made has measurable influence on the efficacy, availability of carcasses on the surface of the ground, and/or the tissue concentrations of chlorophacinone residue.

#3			
Chlorophacinone Treated 3/1-4/06 Bert #4	S060405-17	1.35	6.48
Chlorophacinone Treated 3/1-4/06 Bert #6	S060405-19	0.849	6.66
Chlorophacinone Treated 3/1-4/06 Bert #7	S060405-20	0.974	8.31
Chlorophacinone Treated 3/1-4/06 Bert #8	S060405-21	1.72	7.55
		AVG 1.48	**AVG 5.86**

Table 2: Whole Body and Liver residue analysis for chlorophacinone for prairie dogs fed Rozol to mortality. These carcasses are from MRID# 473336-02.

Sample Description	NWRC ID	Whole Body Average Corrected Conc. (ppm)	Liver Average Corrected Conc. (ppm)
Chlorophacinone Treated 10/30/06 Sallee	S070419-01	0.778	
Chlorophacinone Treated 11/07/06 Hogan 3755905	S070419-02	0.09	0.524
Chlorophacinone Treated 11/07/06 Hogan 3755953	S070419-03	0.222	0.968
Chlorophacinone Treated 12/12/06 NE West Faimon	S070419-04	0.486	1.4
Chlorophacinone Treated 12/14/06 NE West Faimon	S070419-05	1.25	4.02
Chlorophacinone Treated 12/27/06 NE West Faimon	S070419-06	1.06	4.93
Chlorophacinone Treated 3/21/07 Dan Sowers	S070419-07	0.643	3.95
Chlorophacinone Treated 4/01/07 Weiss West	S070419-08	0.13	1.24
Chlorophacinone Treated 11/01/06 Hogan Cottontail Rabbit	S070419-10	0.094	0.448
		AVG 0.528	**AVG 2.185**

Reviewer's Comments:

This study evaluates chlorophacinone residue concentrations in prairie dog tissue and, as a result, makes some progress toward addressing secondary exposure to predators and scavengers. However, carcass handling methods were not described and intermittent thawing and/or other

poor handling practices prior to residue determination do not allow for a conservative determination of chlorophacinone concentrations.

This study suggests that the non-target animal carcass (cottontail rabbit) collected from the study site was killed through chlorophacinone poisoning. The whole body chlorophacinone concentration of the cottontail rabbit was determined to be 0.094 mg/kg. This does not exceed the lowest mammalian LD50 of 0.49 mg/kg (deer mouse; Clark 1994) but chlorophacinone poisoning may still be considered a likely cause of death. Reference doses are generated through a single dose method. In a situation of repeat exposure for several days or more, anticoagulant may circulate in the blood at higher levels and for a longer time than suggested by studies in which only a single, sublethal dose was administered (Belleville 1981). Thus, chlorophacinone concentrations at the time of death may have been low but elevated, prolonged concentrations could have caused mortality. Further, chlorophacinone concentrations may have been higher at the time of death due to possible errors in carcass handling.

Previous studies have determined chlorophacinone residue concentrations for target mammals but this is the first determination of residues in black tailed prairie dogs. This residue study partially addresses the present data gap but further studies are needed to more conservatively assess primary non-target exposure and quantify secondary exposure.

Conclusions:

This study is classified as "supplemental". Though the residue analysis presented in Table 1 may be accurate, the suspected mishandling of carcasses in the other analysis calls into question the handling methods for both analyses.

References:

Belleville, M.J. 1981. Absorption, distribution, metabolism and excretion studies in the rat using ^{14}C-labeled chlorophacinone. Unpubl. report submitted to EPA by Lipha Chemicals, Inc., New York. 14 pp.

Clark, J.P. 1994. Vertebrate Pest Control Handbook. (4th ed.) California Dept. Food and Agriculture, Sacramento. 803 pp.

Marsh, R.E. and W.E. Howard. 1986. Ground squirrel--coyote secondary toxicity studies with chlorophacinone and bromadiolone (an administrative report of laboratory findings). Unpubl. report submitted to EPA by LiphaTech, Inc., Milwaukee, WI.

Fw: Rozol Prairie Dog Bait, EPA Reg. No 7173-286

John Hebert to: Dan Peacock 07/22/2009 01:17 PM

Cc: Meredith Laws

History: This message has been replied to.

Dan - can you follow up on the Lipha's claim that they've already addressed the avian repro conditional requirement? he doesn't say, but this wasn't included with the pdog submission i assume since that came in early '08. does this study sound familiar to you? if it appears that EFED never saw it, we should have them review it. and at the same time have them comment on using the difenacoum study as well.

I'll tell Lipha that they have to get a copy of the difenacoum study review from either Woodstream or through FOIA.

thanks,
john

---- Forwarded by John Hebert/DC/USEPA/US on 07/22/2009 01:07 PM ----

From: "Thomas Schmit" <SchmitT@liphatech.com>
To: John Hebert/DC/USEPA/US@EPA
Cc: "Al Smith" <SmithA@liphatech.com>, "Carl Tanner" <TannerC@liphatech.com>, "Rachel Callies" <CalliesR@liphatech.com>
Date: 07/22/2009 12:37 PM
Subject: Rozol Prairie Dog Bait, EPA Reg. No 7173-286

Dear Mr. Hebert –

This is Liphatech's formal response concerning conditions contained on the Notice of Registration dated May 13, 2009, for Rozol Prairie Dog Bait, EPA Reg. No. 7173-286. Please acknowledge receipt of this response by replying to this e-mail.

Conditions B and C contained in the Notice of Registration for Rozol Prairie Dog Bait requires Liphatech to commit to conduct an avian reproduction within 90 days of the Notice, and to submit the study within 3 years.

Our formal response is: **Liphatech has already submitted an avian reproduction study on Chlorophacinone.** This study was submitted on June 11, 2008, and assigned **MRID number 47323201**.
We have not been provided with the review of this study that we submitted.

The ecological risk assessment conducted for Rozol Prairie Dog Bait (written by Ron Dean, dated November 6, 2008) states: "No acceptable data are available to assess possible reproductive effects to avian species ...".
This study that we submitted is not listed in the "Literature Cited" section of Mr. Dean's assessment, and this suggests that Mr. Dean did not take this study into consideration when conducting his risk assessment.

In addition, we are aware of an avian reproduction study concerning another

anticoagulant rodenticide (difenacoum):

MRID 46799101
Linder, T. (2006) Avian Reproduction Study with Difenacoum in the Japanese Quail (Coturnix coturnix japonica): Final Report. Project Number 04012. Unpublished study prepared by Genesis Laboratories, Inc. 205 p.

Liphatech was a party to the consortium that sponsored this study, and I have attached a copy of the "Letter of Access" authorizing Liphatech to use this data.

We assert that this difenacoum study should be considered here, as it has (along with all the other anticoagulants currently registered) the same mode of action as chlorophacinone. It is appropriate to consider this data in determining whether there is any evidence of reproductive effects from anticoagulants. Given the hierarchy and ranking of rodenticide active ingredients developed during the reregstration process, this difenacoum data can be used to assist in the determination of whether additional studies are necessary for the active ingredient chemicals ranked as lower potential hazard (such as chlorophacinone).

An avian reproduction study is complex, costly and utilizes a very large number of birds. There is significant public pressure to minimize animal testing, and the Office of Pesticide Programs has publicly endorsed this concept.
As a "conditionally required" study, all of the existing data concerning potential reproductive effects from anticoagulants should be carefully considered to determine whether additional studies are necessary and justified.

To conclude:
1. We request a copy of the EPA review document for the chlorophacinone submitted by Liphatech (MRID number 47323201);
2. We request a copy of the EPA review document for the difenacoum study that we have legal access to (MRID number 46799101);
3. We request a specific determination and written notification from EPA stating that Liphatech has, or has not, satisfied the conditions of registration as stated in the Notice of Registration for Rozol Prairie Dog Bait, EPA Reg. No. 7173-286, dated May 13, 2009.

Thank you for your attention to this matter.

Sincerely,

Thomas Schmit
Manager of Regulatory Affairs
Liphatech, Inc.
schmitt@liphatech.com
(414) 410-7230

Letter of access.pdf

SOREX LIMITED
St. Michael's Industrial Estate,
Widnes, Cheshire WA8 8TJ, UK.
Telephone: +44 (0) 151-420 7151
Facsimile: +44 (0) 151-495 1163
Web site: www.sorex.com

16th September 2008

TO WHOM IT MAY CONCERN

We, Sorex Limited of St Michaels Industrial Estate, Widnes, Cheshire WA8 8TJ, United Kingdom, as owners of the following study:

> Linder, T (2006). Avian reproduction study with difenacoum in the Japanese Quail (*Coturnix coturnix japonica*). Genesis Laboratories Inc. Report Number 04012. GLP, unpublished;
>
> Polyakova, L (2007). Storage Stability of Difenacoum Residues in Japanese Quail (*Coturnix coturnix japonica*) tissue Samples. Genesis Laboratories Inc. Report Number 05037. GLP, unpublished;
>
> Polyakova, L (2008). The Residue Analysis of Japanese Quail (*Coturnix coturnix japonica*) Tissues Collected from the Avian Reproduction Test GL Study Number 04012. Genesis Laboratories Inc. Report Number 06008. GLP, unpublished.

hereby provide access to the studies by Liphatech S.A.S. LIPHATECH S.A.S. of Bonnel BP3, 47480 Pond du Casse, FRANCE.

This access is irrevocable and perpetual.

Roger Sharples
Regulatory Affairs Manager

PEST CONTROL
ANIMAL HEALTH
RESEARCH & DEVELOPMENT
TECHNICAL SUPPORT
INTERNATIONAL

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2009–0684; FRL–8436–1]

Receipt of Petition Requesting EPA to Suspend the Registration of Rozol Prairie Dog Bait and Cancel Certain Application Sites; Opening of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is publishing for public comment a June 5, 2009 petition from World Wildlife Fund (WWF) available in docket number EPA–HQ–OPP–2009–0684, requesting that the Agency suspend the registration of the chlorophacinone product, Rozol Prairie Dog Bait (EPA Reg. No. 7173–286), and cancel certain application sites for the product.

DATES: Comments must be received on or before November 6, 2009.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2009–0684, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2009–0684. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Dan Peacock, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5407; fax number: (703) 308–0029; e-mail address: *peacock.dan@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including: Environmental groups; farmers; ranchers; State regulatory partners; other interested Federal agencies; members of the public interested in the sale, distribution, or use of pesticides; and other pesticide registrants and pesticide users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. What Action is the Agency Taking?

EPA is providing an opportunity for public comment on a petition received from the World Wildlife Fund (WWF) that asks the Agency to suspend the registration of Rozol Prairie Dog Bait (EPA Reg. No. 7173–286) and cancel certain application sites for the product. This product is currently registered for use to control black-tailed prairie dogs and its active ingredient is the anticoagulant rodenticide chlorophacinone.

The primary basis for the petition is the potential effect of this product on non-target species, including certain predators and scavengers of the black-tailed prairie dog. Specifically, the petition contends that the poisoning risks to non-target species from the use of this product are unjustified, given the availability of alternative products to control black-tailed prairie dogs. Petitioners request EPA to require the completion of an Avian Reproduction Study before further product use to control black-tailed prairie dogs is permitted. The petition also asks EPA to initiate formal consultation, under section 7 of the Endangered Species Act, with the U.S. Fish and Wildlife Service (FWS) regarding the registration of this product. Third, it requests that EPA develop a memorandum of understanding with FWS to show how EPA will promote the conservation of birds protected under the Migratory Bird Treaty Act. Petitioners ask that EPA suspend the use of Rozol Prairie Dog Bait while these activities are ongoing and also request that the application of the product be prohibited in those counties where black-footed ferrets are present.

As additional background, EPA is providing a recent letters from FWS and other interested parties expressing similar concerns about the potential impact of Rozol Prairie Dog Bait on non-target wildlife protected under the Endangered Species Act and the Migratory Bird Treaty Act (available in the public docket accompanying this notice at EPA–HQ–OPP–2009–0684).

EPA regulates non-food use pesticides, such as Rozol Prairie Dog Bait, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Under FIFRA, EPA registers a pesticide if it determines that the use of the pesticide will not cause "unreasonable adverse effects" to human health or the environment. This standard involves risk-benefit balancing when risks exist above EPA's level of concern. Both registration decision under section 3 of FIFRA and cancellation decisions under section 6 of FIFRA depend on the outcome of adverse effects determinations. If this adverse effects standard is not satisfied, EPA may not register the pesticide and existing pesticides are subject to cancelation. See FIFRA sections 3(c)(5) and 6(b).

If EPA issues a notice of intent to cancel a pesticide registration and further determines that a suspension of the registration prior to the completion of the ensuing cancellation proceedings is necessary to prevent an imminent hazard, EPA may take steps to suspend the registration during the pendency of cancellation proceedings, as described in section 6(c) of FIFRA. FIFRA defines an "imminent hazard" as a situation in which the continued use of a pesticide, during the time required for a cancellation hearing, would likely cause unreasonable adverse effects or will involve an unreasonable hazard to the survival of a species listed as threatened or endangered pursuant to the Endangered Species Act.

WWF's petition requests both suspension of the registration for Rozol Prairie Dog Bait and cancellation of certain application sites for the product. EPA therefore anticipates that its response to the petition will address its risk-benefit analysis for this pesticide. EPA conducted such an analysis at the time it registered Rozol Prairie Dog Bait under section 3 of FIFRA. For this notice, EPA has compiled a list of topics relevant to EPA's risk-benefit balancing decision for Rozol Prairie Dog Bait (available in the public docket accompanying this topic at EPA–HQ–OPP–2009–0684). EPA is providing an opportunity for public comment and the submission of additional information pertinent to these topics (if any is available), as such information would further assist the Agency in responding to the petition.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: September 24, 2009.

Debra Edwards,

Director, Office of Pesticide Programs.

[FR Doc. E9–23932 Filed 10–6–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8967–3]

Proposed Consent Decree, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended ("Act"), 42 U.S.C. 7413(g), notice is hereby given of a proposed consent decree, to address a lawsuit filed by Sierra Club in the United States District Court for the District of Columbia: *Sierra Club* v. *Jackson,* No. 1:09–cv–01028–CKK (D.D.C). Plaintiff filed a deadline suit to compel the Administrator to respond to an administrative petition seeking EPA's objection to a CAA Title V operating permit issued by the Kentucky Department for Environmental Protection, Division for Air Quality to the East Kentucky Power Cooperative William C. Dale Power Station. Under the terms of the proposed consent decree, EPA has agreed to respond to the petition by December 15, 2009.

DATES: Written comments on the proposed consent decree must be received by November 6, 2009.

ADDRESSES: Submit your comments, identified by Docket ID number EPA–HQ–OGC–2009–0763, online at *http://www.regulations.gov* (EPA's preferred method); by e-mail to *oei.docket@epa.gov;* mailed to EPA Docket Center, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; or by hand delivery or courier to EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC, between 8:30 a.m. and 4:30 p.m. Monday through Friday, excluding legal holidays. Comments on a disk or CD–ROM should be formatted in Word or ASCII file, avoiding the use of special characters and any form of encryption, and may be mailed to the mailing address above.

FOR FURTHER INFORMATION CONTACT: Mark Kataoka, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; *telephone:* (202) 564–5584; *fax number:* (202) 564–5603; *e-mail address: kataoka.mark@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Additional Information About the Proposed Consent Decree

This proposed consent decree would resolve a lawsuit alleging that the Administrator failed to perform a nondiscretionary duty to grant or deny, within 60 days of submission, an administrative petition to object to a CAA Title V permit issued by the Kentucky Department for

Pages 316-334 *Access to FIFRA health and safety data is restricted under FIFRA section 10(g)*

first tier toxicology data. The requirement for additional second and third level toxicology testing will be determined by the Agency based on the results of the first tiered studies.

(1) The required first-tier toxicology studies consist of:

(i) Battery of acute studies.

(ii) A subchronic 90–day dermal study or a subchronic 90–day inhalation study.

(iii) An acute and subchronic neurotoxicity screening battery in the rat.

(iv) Prenatal developmental toxicity studies in both the rat and rabbit.

(v) Reproduction and fertility studies in rats.

(vi) Battery of mutagenicity studies.

(vii) Immunotoxicity study.

(2) The conditionally required second-tier studies include:

(i) Subchronic 90–day feeding studies in both the rodent and nonrodent.

(ii) Dermal penetration study.

(3) The conditionally required third-tier studies include:

(i) Chronic feeding studies in the rodent.

(ii) Carcinogenicity.

(iii) Metabolism study.

(iv) Additional mutagenicity testing.

Subpart G— Ecological Effects

§ 158.630 Terrestrial and aquatic nontarget organisms data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget data requirements for a particular pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop and aquatic nonfood use patterns. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products classified under the general use patterns of indoor food and indoor nonfood use.

(2) Data are also required for the general use patterns of forestry and residential outdoor use.

(3) In general, for all outdoor end-uses, including turf, the following studies are required: Two avian oral LD_{50}, two avian dietary LC_{50}, two avian reproduction studies, two freshwater fish LC_{50}, one freshwater invertebrate EC_{50}, one honeybee acute contact LD_{50}, one freshwater fish early-life stage, one freshwater invertebrate life cycle, and three estuarine acute LC_{50}/EC_{50} studies -- fish, mollusk and invertebrate. All other outdoor residential uses, *i.e.*, gardens and ornamental will not usually require the freshwater fish early-life stage, the freshwater invertebrate life-cycle, and the acute estuarine tests.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; TGAI=Technical grade of the active ingredient; TEP=Typical end-use product; PAI=Pure active ingredient; EP=end-use product. Commas between the test substances (*i.e.*, TGAI, TEP) indicate that data may be required on the TGAI or the TEP depending on the conditions set forth in the test note.

(d) *Table.* The following table shows the data requirements for nontarget terrestrial and aquatic organism. The table notes are shown in paragraph (e) of this section.

TERRESTRIAL AND AQUATIC NONTARGET ORGANISM DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry	Residential Outdoor	Greenhouse	Indoor		
Avian and Mammalian Testing									
850.2100	Avian oral toxicity	R	R	R	R	CR	CR	TGAI	1, 2, 3

TERRESTRIAL AND AQUATIC NONTARGET ORGANISM DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry	Residential Outdoor	Greenhouse	Indoor		
850.2200	Avian dietary toxicity	R	R	R	R	NR	NR	TGAI	1, 4
850.2400	Wild mammal toxicity	CR	CR	CR	CR	NR	NR	TGAI	5
850.2300	Avian reproduction	R	R	R	R	NR	NR	TGAI	1, 4
850.2500	Simulated or actual field testing	CR	CR	CR	CR	NR	NR	TEP	6, 7
Aquatic Organisms Testing									
850.1075	Freshwater fish toxicity	R	R	R	R	CR	CR	TGAI, TEP	1, 2, 8, 9, 26
850.1010	Acute toxicity freshwater invertebrates	R	R	R	R	CR	CR	TGAI, TEP	1, 2, 9, 10, 26
850.1025 850.1035 850.1045 850.1055 850.1075	Acute toxicity estuarine and marine organisms	R	R	R	R	NR	NR	TGAI, TEP	1, 9, 11, 12, 26
850.1300	Aquatic invertebrate life cycle (freshwater)	R	R	R	R	NR	NR	TGAI	1, 10, 12
850.1350	Aquatic invertebrate life cycle (saltwater)	CR	CR	CR	CR	NR	NR	TGAI	12, 14, 15
850.1400	Fish early-life stage (freshwater)	R	R	R	R	NR	NR	TGAI	1, 12, 13
850.1400	Fish early-life stage (saltwater)	CR	CR	CR	CR	NR	NR	TGAI	12, 15, 16
850.1500	Fish life cycle	CR	CR	CR	CR	NR	NR	TGAI	17, 18
850.1710 850.1730 850.1850	Aquatic organisms bioavailability, biomagnification, toxicity	CR	CR	CR	CR	NR	NR	TGAI, PAI, degradate	19
850.1950	Simulated or actual field testing for aquatic organisms	CR	CR	CR	CR	NR	NR	TEP	7, 20
Sediment Testing									
850.1735	Whole sediment: acute freshwater invertebrates	CR	CR	CR	CR	NR	NR	TGAI	21
850.1740	Whole sediment: acute marine invertebrates	CR	CR	CR	CR	NR	NR	TGAI	21, 23

TERRESTRIAL AND AQUATIC N

Guideline Number	Data Requirement	Ter tri
	Whole sediment: chronic invertebrates freshwater and marine	CR
Insect Pollinator Testing		
850.3020	Honeybee acute contact toxicity	R
850.3030	Honey bee toxicity of residues on foliage	CR
850.3040	Field testing for pollinators	CR

(e) *Test notes.* The follo notes apply to terrestrial a nontarget organisms data ments in the table to parag this section:

1. Data using the TGAI are req port all outdoor end-use product ing, but not limited to turf. D erally not required to support e ucts in the form of a gas, a hi liquid, a highly reactive solid, corrosive material.

2. For greenhouse and indoor ucts, data using the TGAI are support manufacturing-use prod formulated into these same end or to support end-use products no registered manufacturing- Avian acute oral data are not liquid formulations for greenh door uses. The study is not req is no potential for environments

3. Data are required on one p cies and either one waterfowl s upland game bird species fo aquatic, forestry, and resider uses. Data are preferred on wat land game bird species for indo house uses.

4. Data are required on wate land game bird species.

5. Tests are required based on lower tier toxicology studies, acute and subacute testing, inte tern, and environmental fate o that indicate potential exposur

6. Higher tier testing may be specific use pattern when a re sessment indicates a concern oratory toxicity endpoints and sure assessments.

ENTS—Continued

Indoor	Test substance	Test Note No.
NR	TGAI	1, 4
NR	TGAI	5
NR	TGAI	1, 4
NR	TEP	6, 7
CR	TGAI, TEP	1, 2, 6, 9, 26
CR	TGAI, TEP	1, 2, 9, 10, 26
NR	TGAI, TEP	1, 9, 11, 12, 26
NR	TGAI	1, 10, 12
NR	TGAI	12, 14, 15
NR	TGAI	1, 12, 13
NR	TGAI	12, 15, 16
NR	TGAI	17, 18
NR	TGAI, PAI, degradate	19
NR	TEP	7, 20
IR	TGAI	21
R	TGAI	21, 23

TERRESTRIAL AND AQUATIC NONTARGET ORGANISM DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry	Residential Outdoor	Greenhouse	Indoor		
	Whole sediment: chronic invertebrates freshwater and marine	CR	CR	CR	CR	NR	NR	TGAI	22, 23
Insect Pollinator Testing									
850.3020	Honeybee acute contact toxicity	R	CR	R	R	NR	NR	TGAI	1
850.3030	Honey bee toxicity of residues on foliage	CR	CR	CR	CR	NR	NR	TEP	24
850.3040	Field testing for pollinators	CR	CR	CR	CR	NR	NR	TEP	25

(e) *Test notes.* The following test notes apply to terrestrial and aquatic nontarget organisms data requirements in the table to paragraph (d) of this section:

1. Data using the TGAI are required to support all outdoor end-use product uses including, but not limited to turf. Data are generally not required to support end-use products in the form of a gas, a highly volatile liquid, a highly reactive solid, or a highly corrosive material.

2. For greenhouse and indoor end-use products, data using the TGAI are required to support manufacturing-use products to be reformulated into these same end-use products or to support end-use products when there is no registered manufacturing-use product. Avian acute oral data are not required for liquid formulations for greenhouse and indoor uses. The study is not required if there is no potential for environmental exposure.

3. Data are required on one passerine species and either one waterfowl species or one upland game bird species for terrestrial, aquatic, forestry, and residential outdoor uses. Data are preferred on waterfowl or upland game bird species for indoor and greenhouse uses.

4. Data are required on waterfowl and upland game bird species.

5. Tests are required based on the results of lower tier toxicology studies, such as the acute and subacute testing, intended use pattern, and environmental fate characteristics that indicate potential exposure.

6. Higher tier testing may be required for a specific use pattern when a refined risk assessment indicates a concern based on laboratory toxicity endpoints and refined exposure assessments.

7. Environmental chemistry methods used to generate data associated with this study must include results of a successful confirmatory method trial by an independent laboratory. Test standards and procedures for independent laboratory validation are available as addenda to the guideline for this test requirement.

8. Data are required on one coldwater fish and one warmwater fish for terrestrial, aquatic, forestry, and residential outdoor uses. For indoor and greenhouse uses, testing with only one of either fish species is required.

9. EP or TEP testing is required for any product which meets any of the following conditions:

i. The end-use pesticide will be introduced directly into an aquatic environment (e.g., aquatic herbicides and mosquito larvicides) when used as directed.

ii. The maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment is ≥ one-half the LC_{50} or EC_{50} of the TGAI when the EP is used as directed.

iii. An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms.

10. Data are required on one freshwater aquatic invertebrate species.

11. Data are required on one estuarine/marine mollusk, one estuarine/marine invertebrate and one estuarine/marine fish species.

12. Data are generally not required for outdoor residential uses, other than turf, unless data indicate that pesticide residues from the proposed use(s) can potentially enter waterways.

13. Data are required on one freshwater fish species. If the test speoies is different from the two species used for the freshwater fish acute toxicity tests, a 96-hour LC_{50} on that species must also be provided.

14. Data are required on one estuarine/marine invertebrate species.

15. Data are required on estuarine/marine species if the product meets any of the following conditions:

i. Intended for direct application to the estuarine or marine environment.

ii. Expected to enter this environment in significant concentrations because of its expected use or mobility patterns.

iii. If the acute LC_{50} or EC_{50} < 1 milligram/liter (mg/l).

iv. If the estimated environmental concentration (EEC) in water is ≥ 0.01 of the acute EC_{50} or LC_{50} or if any of the following conditions exist:

A. Studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected.

B. Physicochemical properties indicate bioaccumulation of the pesticide.

C. The pesticide is persistent in water (e.g., half-life in water > 4 days).

16. Data are required on one estuarine/marine fish species.

17. Data are required on estuarine/marine species if the produot is intended for direct application to the estuarine or marine environment, or the product is expected to enter this environment in significant concentrations because of its expected use or mobility patterns.

18. Data are required on freshwater species if the end-use product is intended to be applied directly to water, or is expected to be transported to water from the intended use site, and when any of the following conditions apply:

i. If the estimated environmental concentration (EEC) is ≥ 0.1 of the no-observed-effect level in the fish early-life stage or invertebrate life cycle test;

ii. If studies of other organisms indicate that the reproductive physiology of fish may be affected.

19. Not required when:

i. The octanol/water partition coefficients of the pesticide and its major degradates are < 1,000; or

ii. There are no potential exposures to fish and other nontarget aquatic organisms; or

iii. The hydrolytic half-life is < 5 days at pH 5, 7 and 9.

20. Data are required based on the results of lower tier studies such as acute and chronic aquatic organism testing, intended use pattern, and environmental fate characteristics that indicate significant potential exposure.

21. Data are required if:

i. The half-life of the pesticide in the sediment is ≤ 10 days in either the aerobic soil or aquatic metabolism studies and if any of the following conditions exist:

A. The soil partition coefficient (Kd) is ≥ 50.

B. The log Kow is ≥ 3.

C. The Koc ≥ 1,000.

ii. Registrants must consult with the Agency on appropriate test protocols prior to designing the study.

22. Data are required if:

i. The estimated environmental concentration (EEC) in sediment is > 0.1 of the acute LC_{50}/EC_{50} values and

ii. The half-life of the pesticide in the sediment is > 10 days in either the aerobic soil or aquatic metabolism studies and if any of the following conditions exist:

A. The soil partition coefficient (Kd) is ≥ 50.

B. The log Kow is ≥ 3.

C. The Koc ≥ 1,000.

iii. Registrants must consult with the Agency on appropriate test protocols prior to designing the study.

23. Sediment testing with estuarine/marine test species is required if the product is intended for direct application to the estuarine or marine environment or the product is expected to enter this environment in concentrations which the Agency believes to be significant, either by runoff or erosion, because of its expected use or mobility pattern.

24. Data are required only when the formulation contains one or more active ingredients having an acute LD_{50} of < 11 micrograms per bee as determined in the honey bee acute contact study and the use pattern(s) indicate(s) that honey bees may be exposed to the pesticide.

25. Required if any of the following conditions are met:

i. Data from other sources (Experimental Use Permit program, university research, registrant submittals, etc.) indicate potential adverse effects on colonies, especially effects other than acute mortality (reproductive, behavioral, etc.);

ii. Data from residual toxicity studies indicate extended residual toxicity.

iii. Data derived from studies with terrestrial arthropods other than bees indicate potential chronic, reproductive or behavioral effects.

26. The freshwater fish test species for the TEP testing is the most sensitive of the species tested with the TGAI. Freshwater invertebrate and acute estuarine and marine organisms must also be tested with the EP or TEP using the same species tested with the TGAI.

§ 158.660 Nontarget plant protection data requirements table.

(a) *General.* Sections 158.100 through158.130 describe how to use this table to determine the nontarget plant data requirements for a par ticide product. Notes that a individual test and inclu conditions, qualifications, tions to the designated tes in paragraph (e) of this secti

(b) *Use patterns.* (1) The use pattern includes product under the general use patte restrial food crop, terrestria and terrestrial nonfood. T use pattern includes only t use patterns of aquatic food aquatic nonfood.

TABLE—NONTAR

Guideline Number	Data Require
Nontarget Area Phytotoxicity - Tier I	
850.4100	Seedling emerger
850.4150	Vegetative vigor
850.4400 850.5400	Aquatic plant grov (algal and aqua cular plant toxic
Nontarget Area Phytotoxicity - Tier II	
850.4100	Seedling emergen
850.4150	Vegetative vigor
850.4400 850.5400	Aquatic plant grow (algal and aquat cular plant toxici
Nontarget Area Phytotoxicity - Tier III	
850.4300	Terrestrial field
850.4450	Aquatic field
Target Area Phytotoxicity	
850.4025	Target area phytot

(e) *Test notes.* The follo notes apply to the table in (d) of this section.

1. Not required for containe treatments such as bait b pheromone traps unless adverse ports are received by the Agency.

2. Not required for known phyt

3. Generally not required for gr mulations. May be requested on case basis.

4. Required for known phytotoxi as herbicides, desiccants and defol

5. Required if a tested terrestr exhibits a 25 percent or greater d

To be published
10-7-2009
in Federal Register

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2009–0684; FRL–8436–1]

Receipt of Petition Requesting EPA to Suspend the Registration of Rozol Prairie Dog Bait and Cancel Certain Application Sites; Opening of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is publishing for public comment a June 5, 2009 petition from World Wildlife Fund (WWF) available in docket number EPA–HQ–OPP–2009–0684, requesting that the Agency suspend the registration of the chlorophacinone product, Rozol Prairie Dog Bait (EPA Reg. No. 7173–286), and cancel certain application sites for the product.

DATES: Comments must be received on or before [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2009–0684, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2009–0684. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information

unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Dan Peacock, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5407; fax number: (703) 308–0029; e-mail address: *peacock.dan@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including: Environmental groups; farmers; ranchers; State regulatory partners; other interested Federal agencies; members of the public interested in the sale, distribution, or use of pesticides; and other pesticide registrants and pesticide users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions

regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. What Action is the Agency Taking?

EPA is providing an opportunity for public comment on a petition received from the World Wildlife Fund (WWF) that asks the Agency to suspend the registration of Rozol Prairie Dog Bait (EPA Reg. No. 7173–286) and cancel certain application sites for the product. This product is currently registered for use to control black-tailed prairie

dogs and its active ingredient is the anticoagulant rodenticide chlorophacinone.

The primary basis for the petition is the potential effect of this product on non-target species, including certain predators and scavengers of the black-tailed prairie dog. Specifically, the petition contends that the poisoning risks to non-target species from the use of this product are unjustified, given the availability of alternative products to control black-tailed prairie dogs. Petitioners request EPA to require the completion of an Avian Reproduction Study before further product use to control black-tailed prairie dogs is permitted. The petition also asks EPA to initiate formal consultation, under section 7 of the Endangered Species Act, with the U.S. Fish and Wildlife Service (FWS) regarding the registration of this product. Third, it requests that EPA develop a memorandum of understanding with FWS to show how EPA will promote the conservation of birds protected under the Migratory Bird Treaty Act. Petitioners ask that EPA suspend the use of Rozol Prairie Dog Bait while these activities are ongoing and also request that the application of the product be prohibited in those counties where black-footed ferrets are present.

As additional background, EPA is providing a recent letters from FWS and other interested parties expressing similar concerns about the potential impact of Rozol Prairie Dog Bait on non-target wildlife protected under the Endangered Species Act and the Migratory Bird Treaty Act (available in the public docket accompanying this notice at EPA–HQ–OPP–2009–0684).

EPA regulates non-food use pesticides, such as Rozol Prairie Dog Bait, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Under FIFRA, EPA registers a pesticide if it determines that the use of the pesticide will not cause "unreasonable adverse effects" to human health or the environment. This standard involves risk-benefit balancing when risks exist above EPA's level of concern. Both registration decision under section 3 of FIFRA and cancellation decisions under section 6 of FIFRA depend on the outcome of adverse effects determinations. If this adverse effects standard is not satisfied, EPA may not register the pesticide and existing pesticides are subject to cancelation. See FIFRA sections 3(c)(5) and 6(b).

If EPA issues a notice of intent to cancel a pesticide registration and further determines that a suspension of the registration prior to the completion of the ensuing cancellation proceedings is necessary to prevent an imminent hazard, EPA may take steps to suspend the registration during the pendency of cancellation proceedings, as described in section 6(c) of FIFRA. FIFRA defines an "imminent hazard" as a situation in which the continued use of a pesticide, during the time required for a cancellation hearing, would likely cause unreasonable adverse effects or will involve an unreasonable hazard to

the survival of a species listed as threatened or endangered pursuant to the Endangered Species Act.

WWF's petition requests both suspension of the registration for Rozol Prairie Dog Bait and cancellation of certain application sites for the product. EPA therefore anticipates that its response to the petition will address its risk-benefit analysis for this pesticide. EPA conducted such an analysis at the time it registered Rozol Prairie Dog Bait under section 3 of FIFRA. For this notice, EPA has compiled a list of topics relevant to EPA's risk-benefit balancing decision for Rozol Prairie Dog Bait (available in the public docket accompanying this topic at EPA–HQ–OPP–2009–0684). EPA is providing an opportunity for public comment and the submission of additional information pertinent to these topics (if any is available), as such information would further assist the Agency in responding to the petition.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: September 24, 2009.

Debra Edwards,

Director, Office of Pesticide Programs.

[FR Doc. 09–????? Filed ??–??–09; 8:45 am]

BILLING CODE 6560–50–S

Items Added to the Docket as of 9/29/2009

1. IRB Efficacy Review by Bill Jacobs dated 2/11/2009
2. Registration Notice dated 5/13/2009
3. Letter from World Wildlife Fund dated June 5, 2009
4. Letter from Montana Department of Agriculture to EPA dated 9/14/2009
5. Letter from WAFWA to EPA dated 9/19/2008
6. Letter from FWS to EPA dated 5/5/2006
7. Letter from NE Game and Parks Commission to NE Dept. of Agriculture dated 1/18/2006
8. Letter from FWS to NE Dept. of Agriculture dated 1/13/2006
9. Letter from The Wildlife Society to EPA dated 8/17/2009
10. EFED Hazard Assessment (2 Reviews) by Andrew Shelby dated September 3, 2009
    a. "Non-target exposure review of 'Field Efficacy and Hazards of Rozol Bait for Controlling Black-Tailed Prairie Dogs (*Cynomys ludovicianus*)'"
    b. "Secondary exposure review of 'Determination of Chlorophacinone Residues in Prairie Dog Whole Body and Liver Tissues'"
11. EFED Ecological Risk Assessment by Jon Angier and Ron Dean dated November 6, 2008
12. Letter from Debbie Edwards to WWF dated September 28, 2009

Items to be Added to the Docket

1. List of questions for the public

Updated Docket List
Jennifer Gaines to: Dan Peacock 10/01/2009 06:40 AM

Good morning Dan,

I don't think I sent this updated list to you so here it is. Please let me know if you think anything else should be added. As of now, these are all the letters/correspondence we have received/sent.

Thanks,
Jennifer

Jennifer Gaines
Wildlife Biologist
U.S. Environmental Protection Agency
Insecticide-Rodenticide Branch
Registration Division (7505P)

Tel: 703 305-5967
Fax: 703 305-6309


Items Added to the Docket as of 9.doc

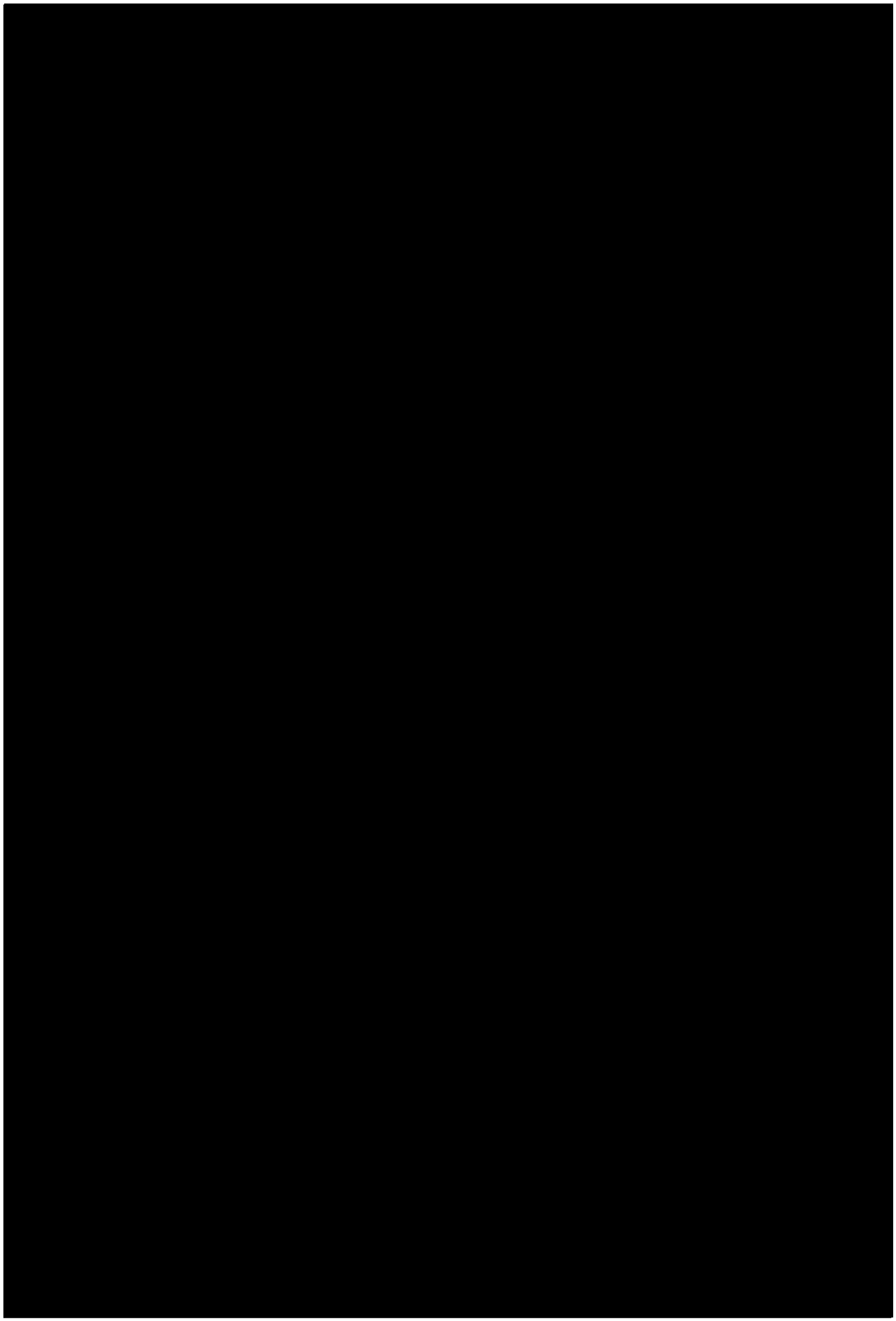
Items Added to the Docket as of 9/29/2009

1. IRB Efficacy Review by Bill Jacobs dated 2/11/2009
2. Registration Notice dated 5/13/2009
3. Letter from World Wildlife Fund dated June 5, 2009
4. Letter from Montana Department of Agriculture to EPA dated 9/14/2009
5. Letter from WAFWA to EPA dated 9/19/2008
6. Letter from FWS to EPA dated 5/5/2006
7. Letter from NE Game and Parks Commission to NE Dept. of Agriculture dated 1/18/2006
8. Letter from FWS to NE Dept. of Agriculture dated 1/13/2006
9. Letter from The Wildlife Society to EPA dated 8/17/2009
10. EFED Hazard Assessment (2 Reviews) by Andrew Shelby dated September 3, 2009
    a. "Non-target exposure review of 'Field Efficacy and Hazards of Rozol Bait for Controlling Black-Tailed Prairie Dogs (*Cynomys ludovicianus*)'"
    b. "Secondary exposure review of 'Determination of Chlorophacinone Residues in Prairie Dog Whole Body and Liver Tissues'"
11. EFED Ecological Risk Assessment by Jon Angier and Ron Dean dated November 6, 2008
12. Letter from Debbie Edwards to WWF dated September 28, 2009

Items to be Added to the Docket

1. List of questions for the public

Internal deliberative information



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM **DATE: 2 October 2009**

SUBJECT: **Reply to Formal Response Concerning Use of Two Avian Reproduction Studies to Fulfill Notice of Registration Requirement for Chlorophacinone**

FROM: **Andrew Shelby, Physical Scientist**
Environmental Fate and Effects Division, Environmental Risk Branch II

THRU: **Tom Bailey, Branch Chief** for Tom Bailey 10/2/09
Environmental Fate and Effects Division, Environmental Risk Branch II

TO: **Dan Peacock, Biologist**
Registration Division, Insecticide Rodenticide Branch

The Agency has reviewed the request to waive the avian reproduction study data requirement for chlorophacinone submitted by Liphatech Inc. The Agency is unable to accept the two studies suggested to fulfill this requirement for the reasons outlined below.

The first suggested study was "Subacute and Subchronic Toxicity of Chlorophacinone in Japanese Quail" (MRID 47323201) published in the Archives of Experimental Veterinary Medicine. While we reserve the discretion to include open literature studies in our risk assessments, we cannot accept this open literature study as a replacement for the avian reproduction study requirement. Over 90% of the avian reproduction endpoints are not measured. Though total mass of eggs and eggs per hen are measured, embryo survival endpoints, hatching endpoints and hatchling survival endpoints are not determined. Finally, raw data is not included disallowing independent validation of the results.

The second suggested study was "Avian Reproduction Study with Difenacoum in the Japanese Quail" (MRID 46799101). Chlorophacinone and difenacoum are very distinct chemicals. Treating difenacoum as a surrogate chemical is inappropriate and cannot be justified without an acceptable bridging strategy. Disparate chemical structures preclude the acceptance of this study for fulfilling the avian reproduction data gap for chlorophacinone.

Please refer to OPPTS Harmonized Test Guideline 850.2300 for a more thorough explanation as to how to fulfill this data requirement. The Agency welcomes constructive comments and suggestions through the registration process. However, your formal response does not satisfy conditions of our May 13, 2009 Notice of Registration to your company. For further consideration of this new use registration of Rozol, acceptable avian reproduction studies on two species must be submitted in accordance with registration timelines.

Reply to Formal Response Concerning Use of Two Avian Reproduction Studies to Fulfill Notice of Registration Requirement for Chlorophacinone

Andrew Shelby to: Dan Peacock 10/02/2009 02:29 PM

Cc: John Hebert, Meredith Laws, Tom Bailey, Jean Holmes

History: This message has been forwarded.

Dan,

Find attached the final memo.

Avian Repro Rebuttal.doc Avian Repro Rubuttal.PDF

Thanks,

Andrew Shelby, Physical Scientist
U.S. Environmental Protection Agency
OPPTS/OPP/EFED/ERB2
P: 703-347-0119

Re: Final version of letter to Liphatech rejecting chlorophacione data waiver request

Laura Parsons to: Andrew Shelby 10/02/2009 04:03 PM

Cc: Angel Chiri, Bill Jacobs, Dan Peacock, Edward Odenkirchen, Jennifer Gaines, John Hebert, Kit Farwell, Mary Powell, Nicholas Mastrota, Quentin Borges-Silva, Russell Wasem, Shannon Borges, Tom Bailey, William Erickson

Thanks Andrew,

I had drafted comments, but was interrupted and did not finish them. This version addresses my concerns on your earlier draft. Nice job.

LP

Andrew Shelby | Rodenticide team, Unless I got back to you on s... | 10/02/2009 03:54:22 PM

From:	Andrew Shelby/DC/USEPA/US
To:	Angel Chiri/DC/USEPA/US@EPA, Bill Jacobs/DC/USEPA/US@EPA, Dan Peacock/DC/USEPA/US@EPA, Edward Odenkirchen/DC/USEPA/US@EPA, Jennifer Gaines/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA, Kit Farwell/DC/USEPA/US@EPA, Laura Parsons/DC/USEPA/US@EPA, Mary Powell/DC/USEPA/US@EPA, Nicholas Mastrota/DC/USEPA/US@EPA, Quentin Borges-Silva/DC/USEPA/US@EPA, Russell Wasem/DC/USEPA/US@EPA, Shannon Borges/DC/USEPA/US@EPA, Tom Bailey/DC/USEPA/US@EPA, William Erickson/DC/USEPA/US@EPA
Date:	10/02/2009 03:54 PM
Subject:	Final version of letter to Liphatech rejecting chlorophacione data waiver request

Rodenticide team,

Unless I got back to you on specific comments, all of your comments should be incorporated in this final draft.

[attachment "Avian Repro Rebuttal.doc" deleted by Laura Parsons/DC/USEPA/US]

Andrew Shelby, Physical Scientist
U.S. Environmental Protection Agency
OPPTS/OPP/EFED/ERB2
P: 703-347-0119

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DP: 350010

MEMORANDUM

Sept 3, 2009

SUBJECT: Chlorophacinone (067707): Non-target exposure review of "Field Efficacy and Hazards of Rozol Bait for Controlling Black-Tailed Prairie Dogs (*Cynomys ludovicianus*)"

FROM: Andrew Shelby, MSES, MPA
Environmental Fate and Effects Division/ERB2 (MC 7507P)

SECONDARY REVIEW: Jean Holmes, DVM, MPH
Environmental Fate and Effects Division/ERB2
Edward Odenkirchen, Ph. D.
Environmental Fate and Effects Division/ERB1

THRU: Tom Bailey, Branch Chief
Environmental Fate and Effects Division/ERB2 (MC 7507P)

TO: Dan Peacock
Registration Division/IRB (MC 7505P)

Attached is EFED's review of the hazard components for two studies: "Field Efficacy and Hazards of Rozol Bait for Controlling Black-Tailed Prairie Dogs (*Cynomys ludovicianus*)" and "Determination of Chlorophacinone Residues in Prairie Dog Whole Body and Liver Tissues". Registration Division has reviewed the efficacy component of these studies. The major objectives of the studies were to verify efficacy of Rozol Prairie Dog Bait (chlorophacinone 0.005% a.i.) when used for black-tailed prairie dogs and determine chlorophacinone residue concentrations in the resulting carcasses. The studies provide some insight into non-target primary exposure by assessing amount of bait moved to ground surface, however EFED believes a more robust set of carcass and bait searches would be required to reduce the risk of secondary exposure to predators and scavengers of black-tailed prairie dogs. The attached documents review the field hazard study and residue analysis from the perspective of characterizing the primary and secondary exposure potential to non-target animals.

EFED concludes that the hazard component of the attached field study provides limited information regarding non-target primary exposure and is totally insufficient for evaluating non-target secondary exposure. Non-target exposure assessment could be improved if: (1) populations of potential non-target exposed animals were assessed prior to initiation of the study; (2) target animal carcasses were monitored and left for scavenging/predation for longer periods of time; (3) a carcass recovery efficiency test was performed; and (4) carcass search areas were expanded to include ranges of all potentially exposed non-target animals to ensure that study mortalities are not lost due to a small search area. The primary weakness of this study is its attempt to combine field efficacy with non-target exposure. Carcass collection should occur frequently in a field efficacy study to best estimate mortality without the influence of scavenging and predation. In a secondary exposure study, predators and scavengers should be given ample opportunity to feed on carcasses to maximize hazard. This study attempted to combine these methods resulting in unreliable information regarding the hazard component.

EFED further concludes that the attached residue analysis could be improved if carcass handling techniques were explicitly stated and followed. Evidence indicates carcass handling techniques differed between the two residue analyses performed in the study though this cannot be confirmed for lack of explicit methods. The resulting data preclude conservative study results.

Reviewed for non-target exposure, the field efficacy study is classified as "invalid". The residue analysis is classified as "supplemental".

Contact Andrew Shelby at 703-347-0119 if you have any questions.

Rodenticide: Chlorophacinone (067707)

Rozol Prairie Dog Bait

Study Sponsor: Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209

Performing Laboratory: Charles D. Lee
Department of Animal Sciences and Industry
Kansas State University Research and Extension
Room 131 Call Hall
Manhatten, KS 66506

Reviewer: Andrew Shelby, Physical Scientist, ERB2/EFED

Study Classification:

Chlorophacinone (067707): Secondary exposure review of "Field Efficacy and Hazards of Rozol Bait for Controlling Black-Tailed Prairie Dogs (*Cynomys ludovicianus*)"

Data Evaluation Review Summary
The major objective of the study was to determine efficacy of Rozol Prairie Dog Bait (chlorophacinone 0.005% a.i.) when used to control black-tailed prairie dogs. For assessment of the efficacy component, please see the review performed by Registration Division. The study also purports to provide insight into non-target primary exposure by assessing amount of bait moved to ground surface and collecting non-target carcasses. However, neither primary nor secondary non-target risks were adequately assessed due to carcass searches occurring too infrequently and over limited ranges. To adequately assess these risks, the following methods would need to be included: a non-target field census; a carcass recovery efficiency test; expansion of carcass search areas; and carcass monitoring rather than carcass collection.

Study Purpose:
1. Determine the efficacy of Rozol Prairie Dog Bait in controlling black-tailed prairie dogs, when applied in-burrow, at the rate of ¼ cup of bait per active burrow.
2. Determine the (approximate) number of prairie dogs that are available after death to predators/scavengers on the surface of the ground
3. Determine the amount of granules of Rozol Prairie Dog Bait that are moved to the ground surface, out of the burrows, by the normal activity of prairie dogs, predators and scavengers of prairie dogs, or by other wildlife, livestock or domestic animals
4. Provide carcasses of black-tailed prairie dogs collected from treated areas, for tissue analysis to determine whole-body and liver concentrations of chlorophacinone residue
5. Determine if the time of year when application is made has measurable influence on the efficacy, availability of carcasses on the surface of the ground, and/or the tissue concentrations of chlorophacinone residue.

Study Sites and Treatments:
The study was conducted in three different areas. Treated sites ranged in size from 2.1 acres to 41.5 acres.

Trial 1 was located in areas of Barton and Safford Counties near the community of Great Bend, Kansas. The elevation at the control site was approximately 1820 feet above sea level, with the soils described as the Kisiwa loam, fairly flooded. Elevation at the Salle test site is approximately 2024 feet and the soil is described as Naron fine loam with 1-3% slopes. The elevation at the Hogan site is 2012 feet and soils are Pratt-Carwile complex with 0-5% slope.

Trial 2 had the control site and two test sites located in Rawlins County, Kansas near the community of Atwood, Kansas. The elevation at the Ryan Cemetery is approximately 3045 feet, the elevation at Ryan SE is approximately 3009 feet and at Ryan Control is 3015 feet. Soils at Ryan SE and Ryan Control are described as Colby silt loam with 10-15% slopes. The other two test sites for Trial 2 were located in the edge of Nebraska in Hitchcock County south of Trenton, Nebraska. The site labeled NE East Lashley is about 3045 feet above sea level with Colby silt loam soils with 9-30% slopes. The NE West Faiman site is about 2966 feet in elevation and the soils are Colby silt loam with 9-30% slopes.

Trial 3 had the control site and all four test sites located near Benkleman, Nebraska. Wiese East is approximately 3060 feet in elevation and has soils described as Sulco loam with slopes 3-6%. Weise West is 3176 feet in elevation and soils are Sulco loam with slopes of 9-30%. The Sowers site is about 3300 feet in elevation with soils described as Colby silt loam with 5-15% slopes. The control site is 3269 feet in elevation with soils described as Valent sand, rolling.

Each plot encompassed a prairie dog colony that contained at least 20 individual animals. To prevent immigration of prairie dogs from outside the treated plot during the trial, the plots selected were physically separated from areas occupied by prairie dogs near roadways, other natural or artificial barriers, or large areas of land not occupied by prairie dogs.

All sites were native rangeland with primarily short grass species and had been grazed by cattle prior to the trial.

Methods:

Efficacy determination:
Census of study plots: A "Visual Count Index" was the direct census method used to estimate prairie dog populations. A "Plugged Burrow Index" was used as a confirmatory (indirect) census method. Both census methods were used before and after the baiting application period, with the Visual Count Index taken before the Plugged Burrow Index, on both the treated plot and the control plot. The pre-treatment census was taken no more than 4 days prior to application of the bait. If inclement weather conditions disrupted normal activity of the prairie dogs, the post-treatment census will be taken as soon as weather conditions stabilized.

The census of the control plot was made within 24 hours before or after the corresponding census was taken on the treated plot.

Bait application: Application of the test substance bait was made by a qualified applicator, who holds the appropriate license for the state where the study plots were located. Application of the test substance bait was made no more than 2 days following the pre-treatment census, and the day of bait application was indicated as Day 0 of the study. Bait application was made to all active prairie dog burrows; that were identified by visual observation of burrow openings; that were generally free of leaves, seeds, other debris or spider webs, and/or showed freshly turned earth, and/or had prairie dog feces nearby. No control substance (placebo bait) was applied to the control plot.

Design for carcass availability on the ground surface:
A methodical carcass search of the complete treated plot and control plot was conducted every other day until termination of the study, to recover all carcasses of both target and non-target animals. These trials are necessary to accurately assess target and non-target animal mortality. Relevant data concerning the time of recovery, species, sex, age (adult vs. juvenile) and condition of the carcass was recorded. The carcass search area extended about 100 feet in all directions beyond the boundaries of the study plots, but was smaller when limited by natural boundaries or property access denial. Carcass searches were conducted during the afternoon hours (weather permitting) to minimize the availability of carcasses to nocturnal predators/scavengers.

All sightings of non-target birds and mammals on or near the study plots were recorded. Any non-target mammal carcasses found on or near the study plots were frozen as soon as possible and submitted to the USDA National Wildlife Research Center (NWRC) for necropsy and analysis.

Design for bait availability on the ground surface:
A methodical bait search of the treated plot was conducted on days 1 through 7 of the study, in order to document whether granules of Rozol Prairie Dog Bait had been moved to the ground surface, or out of the burrows by the normal activity of prairie dogs, predators and scavengers of prairie dogs, or by other wildlife, livestock or domestic animals. The control plot was not searched.

Due to the large number of burrows treated, the bait search was made on 50 burrows that were located along two perpendicular transect lines. Every active burrow where bait was placed was examined for bait visible on the surface of the ground or less than six inches into the burrow. Observations noted any disturbance of the ground, the presence of any predators, scavengers, or other non-target birds or mammals, such as tracks, droppings, scratchings, markings, or any other recognizable sign.

Design for tissue analysis to determine chlorophacinone residues:
All recovered prairie dog carcasses were sent to the USDA NWRC for analysis of chlorophacinone residue levels. Data concerning the location, time of recovery, species, sex, age and condition of the carcass were recorded. Carcasses were frozen as soon as possible, and marked and handled according to SOPs. Further methods will be described from a NWRC report.

RESULTS

Population change: Burrow activity declined dramatically in all colonies treated with Rozol. Burrow activity dropped 95% when comparing activity before versus after treatment and a reduction of 84% when comparing untreated versus treated colonies. No observed differences in efficacy were found across the three treatment periods (Fall, Early Winter, and Late Winter) at alpha = 0.05.

Visual counts of prairie dogs declined dramatically in all colonies treated with Rozol. An observed reduction in counts of 94% was found when comparing counts before versus after treatment and a reduction of 96% when comparing untreated versus treated colonies. No effects of environmental conditions on visual counts of prairie dogs were found.

Carcass Availability: During the entire study, only 10 carcasses were found aboveground (9 black-tailed prairie dogs and 1 cottontail) in 5 of the 10 treated colonies. One carcass was found in each of 2 colonies, 2 carcasses were found in 1 colony and 3 carcasses were found in each of 2 colonies. All carcasses were found within the treated areas of the colonies. Carcasses were only found 10 to 25 days (mean = 15.2) after application and most carcasses were found on day 12 of the study. Also observed were 5 impaired prairie dogs in 2 treated colonies at least 10 days after application.

Transects were estimated to search for carcasses with an effective observational width of 200 feet with length ranging from 450 to 2100 feet. The total area is searched every other day for up to 25 days was 143.7 acres. Therefore, the density of carcasses observed above ground due to Rozol intoxication was 0.07 per acre or 1 carcass per 14 acres.

Reviewer's Comments:

The study was designed primarily to determine field efficacy of Rozol Prairie Dog Bait to fulfill product performance data requirements (40 CFR §158.640). Secondary emphasis was placed on determining hazards of bait application to non-target granivores and carcass availability to predators and scavengers. Carcass collection is inappropriate for evaluating secondary exposure hazard because it artificially reduces opportunity for secondary exposure. Rather, it is necessary to monitor carcasses. Carcass monitoring maximizes hazard by allowing predators and scavengers opportunity to feed on poisoned carcasses. This strategy also allows the investigator to determine what type of animal scavenged the carcass. Carcass monitoring can only be carried out effectively with frequent carcass searches. Diurnal and nocturnal predators and scavengers will scavenge carcasses very quickly after they are available. The investigators in this study performed carcass searches and removal every 48 hours when evidence suggests that 12 hour carcass monitoring intervals are more appropriate to account for rapid feeding on carcasses. Though more frequent searches would allow investigators to find more carcasses, many poisoned carcasses would still go unfound. To address this, a carcass search efficiency test should be implemented. Finally, carcass search areas should be large enough to account for non-target animal ranges that are at risk of exposure as determined by the pretreatment non-target animal census. Between too infrequent carcass searches, lacking a carcass search efficiency test and

insufficient search ranges, the investigators have significantly underestimated target, non-target primary and non-target secondary exposure.

Hazards to primary and secondarily exposed non-target animals could have been more effectively assessed. Impacts to non-target animal populations can be determined through a variety of techniques including mark-recapture, radio telemetry, catch per unit effort and/or burrow censussing to index population sizes before and after treatment. Carcass monitoring can be implemented using infrared video cameras, a photography system or other conventional methods.

Conclusions:

This study is classified as invalid for addressing the secondary exposure data gap. Carcass searches were too narrow, non-target populations were not monitored, and applications did not maximize risk. Consultation with EFED is suggested for the design of a secondary exposure study.

References:

Marsh, R.E. and W.E. Howard. 1986. Ground squirrel--coyote secondary toxicity studies with chlorophacinone and bromadiolone (an administrative report of laboratory findings). Unpubl. report submitted to EPA by LiphaTech, Inc., Milwaukee, WI.

Rodenticide: Chlorophacinone (067707)

Study Sponsor: Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209

Performing Laboratory: US Department of Agriculture
National Wildlife Research Center
4101 LaPorte Avenue
Fort Collins, CO 80521

Reviewer: Andrew Shelby, Physical Scientist, ERB2/EFED

Study Classification:

Chlorophacinone (067707): Secondary exposure review of "Determination of Chlorophachinone Residues in Prairie Dog Whole Body and Liver Tissues"

Summary:

This study determines the liver and whole body chlorophacinone residues for prairie dog carcasses collected from "Field Efficacy and Hazards of Rozol Bait for Controlling Black-Tailed Prairie Dogs (*Cynomys ludovicianus*)" (MRID 47333602) and an additional study involving chlorophacinone applications. Laboratory quality control methods in detection of the chemical proved effective but the handling of samples is not discussed and chemical degradation may have occurred as a result. Degradation is suspected because two sets of prairie dog carcasses analyzed, both fed Rozol Bait to mortality, had significantly different chlorophacinone residue levels. The analysis with higher residue concentrations (Table 1) consisted of samples all collected within a three day period. Samples collected for the second analysis (Table 2) were collected over a span of five months. This discrepancy in collection periods could account for differences in the handling of specimens and differences in degradation. Though this may be the cause, the reason for the discrepancy cannot be determined as handling methods are not described.

Table 1: Whole Body and Liver residue analysis for chlorophacinone for prairie dogs fed Rozol to mortality. These carcasses are from a study unassociated with MRID# 473336-02.

Sample Description	NWRC ID	Whole Body Average Corrected Conc. (ppm)	Liver Average Corrected Conc. (ppm)
Found Dead East Pasture 3/30/06	S060503-6	1.72	3.62
Chlorophacinone Treated 3/1-4/06 Bert #1	S060405-14	1.22	3.28
Chlorophacinone Treated 3/1-4/06 Bert #2	S060405-15	1.73	4.28
Chlorophacinone Treated 3/1-4/06 Bert	S060405-16	2.24	6.66

#3			
Chlorophacinone Treated 3/1-4/06 Bert #4	S060405-17	1.35	6.48
Chlorophacinone Treated 3/1-4/06 Bert #6	S060405-19	0.849	6.66
Chlorophacinone Treated 3/1-4/06 Bert #7	S060405-20	0.974	8.31
Chlorophacinone Treated 3/1-4/06 Bert #8	S060405-21	1.72	7.55
		AVG 1.48	**AVG 5.86**

Table 2: Whole Body and Liver residue analysis for chlorophacinone for prairie dogs fed Rozol to mortality. These carcasses are from MRID# 473336-02.

Sample Description	NWRC ID	Whole Body Average Corrected Conc. (ppm)	Liver Average Corrected Conc. (ppm)
Chlorophacinone Treated 10/30/06 Sallee	S070419-01	0.778	
Chlorophacinone Treated 11/07/06 Hogan 3755905	S070419-02	0.09	0.524
Chlorophacinone Treated 11/07/06 Hogan 3755953	S070419-03	0.222	0.968
Chlorophacinone Treated 12/12/06 NE West Faimon	S070419-04	0.486	1.4
Chlorophacinone Treated 12/14/06 NE West Faimon	S070419-05	1.25	4.02
Chlorophacinone Treated 12/27/06 NE West Faimon	S070419-06	1.06	4.93
Chlorophacinone Treated 3/21/07 Dan Sowers	S070419-07	0.643	3.95
Chlorophacinone Treated 4/01/07 Weiss West	S070419-08	0.13	1.24
Chlorophacinone Treated 11/01/06 Hogan Cottontail Rabbit	S070419-10	0.094	0.448
		AVG 0.528	**AVG 2.185**

Reviewer's Comments:

This study evaluates chlorophacinone residue concentrations in prairie dog tissue and, as a result, makes some progress toward addressing secondary exposure to predators and scavengers. However, carcass handling methods were not described and intermittent thawing and/or other

poor handling practices prior to residue determination do not allow for a conservative determination of chlorophacinone concentrations.

This study suggests that the non-target animal carcass (cottontail rabbit) collected from the study site was killed through chlorophacinone poisoning. The whole body chlorophacinone concentration of the cottontail rabbit was determined to be 0.094 mg/kg. This does not exceed the lowest mammalian LD50 of 0.49 mg/kg (deer mouse; Clark 1994) but chlorophacinone poisoning may still be considered a likely cause of death. Reference doses are generated through a single dose method. In a situation of repeat exposure for several days or more, anticoagulant may circulate in the blood at higher levels and for a longer time than suggested by studies in which only a single, sublethal dose was administered (Belleville 1981). Thus, chlorophacinone concentrations at the time of death may have been low but elevated, prolonged concentrations could have caused mortality. Further, chlorophacinone concentrations may have been higher at the time of death due to possible errors in carcass handling.

Previous studies have determined chlorophacinone residue concentrations for target mammals but this is the first determination of residues in black tailed prairie dogs. This residue study partially addresses the present data gap but further studies are needed to more conservatively assess primary non-target exposure and quantify secondary exposure.

Conclusions:

This study is classified as "supplemental". Though the residue analysis presented in Table 1 may be accurate, the suspected mishandling of carcasses in the other analysis calls into question the handling methods for both analyses.

References:

Belleville, M.J. 1981. Absorption, distribution, metabolism and excretion studies in the rat using ^{14}C-labeled chlorophacinone. Unpubl. report submitted to EPA by Lipha Chemicals, Inc., New York. 14 pp.

Clark, J.P. 1994. Vertebrate Pest Control Handbook. (4th ed.) California Dept. Food and Agriculture, Sacramento. 803 pp.

Marsh, R.E. and W.E. Howard. 1986. Ground squirrel--coyote secondary toxicity studies with chlorophacinone and bromadiolone (an administrative report of laboratory findings). Unpubl. report submitted to EPA by LiphaTech, Inc., Milwaukee, WI.

Fw: Rozol Prairie Dog Bait, EPA Reg. No 7173-286

John Hebert to: Dan Peacock 07/22/2009 01:17 PM
Cc: Meredith Laws

History: This message has been replied to.

Dan - can you follow up on the Lipha's claim that they've already addressed the avian repro conditional requirement? he doesn't say, but this wasn't included with the pdog submission i assume since that came in early '08. does this study sound familiar to you? if it appears that EFED never saw it, we should have them review it. and at the same time have them comment on using the difenacoum study as well.

I'll tell Lipha that they have to get a copy of the difenacoum study review from either Woodstream or through FOIA.

thanks,
john
----- Forwarded by John Hebert/DC/USEPA/US on 07/22/2009 01:07 PM -----

From:	"Thomas Schmit" <SchmitT@liphatech.com>
To:	John Hebert/DC/USEPA/US@EPA
Cc:	"Al Smith" <SmithA@liphatech.com>, "Carl Tanner" <TannerC@liphatech.com>, "Rachel Callies" <CalliesR@liphatech.com>
Date:	07/22/2009 12:37 PM
Subject:	Rozol Prairie Dog Bait, EPA Reg. No 7173-286

Dear Mr. Hebert –

This is Liphatech's formal response concerning conditions contained on the Notice of Registration dated May 13, 2009, for Rozol Prairie Dog Bait, EPA Reg. No. 7173-286. Please acknowledge receipt of this response by replying to this e-mail.

Conditions B and C contained in the Notice of Registration for Rozol Prairie Dog Bait requires Liphatech to commit to conduct an avian reproduction within 90 days of the Notice, and to submit the study within 3 years.

Our formal response is: **Liphatech has already submitted an avian reproduction study on Chlorophacinone.** This study was submitted on June 11, 2008, and assigned **MRID number 47323201**.
We have not been provided with the review of this study that we submitted.

The ecological risk assessment conducted for Rozol Prairie Dog Bait (written by Ron Dean, dated November 6, 2008) states: "No acceptable data are available to assess possible reproductive effects to avian species ...".
This study that we submitted is not listed in the "Literature Cited" section of Mr. Dean's assessment, and this suggests that Mr. Dean did not take this study into consideration when conducting his risk assessment.

In addition, we are aware of an avian reproduction study concerning another

anticoagulant rodenticide (difenacoum):

> MRID 46799101
> Linder, T. (2006) Avian Reproduction Study with Difenacoum in the Japanese Quail (Coturnix coturnix japonica): Final Report. Project Number 04012. Unpublished study prepared by Genesis Laboratories, Inc. 205 p.

Liphatech was a party to the consortium that sponsored this study, and I have attached a copy of the "Letter of Access" authorizing Liphatech to use this data.

We assert that this difenacoum study should be considered here, as it has (along with all the other anticoagulants currently registered) the same mode of action as chlorophacinone. It is appropriate to consider this data in determining whether there is any evidence of reproductive effects from anticoagulants. Given the hierarchy and ranking of rodenticide active ingredients developed during the reregstration process, this difenacoum data can be used to assist in the determination of whether additional studies are necessary for the active ingredient chemicals ranked as lower potential hazard (such as chlorophacinone).

An avian reproduction study is complex, costly and utilizes a very large number of birds. There is significant public pressure to minimize animal testing, and the Office of Pesticide Programs has publicly endorsed this concept.
As a "conditionally required" study, all of the existing data concerning potential reproductive effects from anticoagulants should be carefully considered to determine whether additional studies are necessary and justified.

To conclude:
1. We request a copy of the EPA review document for the chlorophacinone submitted by Liphatech (MRID number 47323201);
2. We request a copy of the EPA review document for the difenacoum study that we have legal access to (MRID number 46799101);
3. We request a specific determination and written notification from EPA stating that Liphatech has, or has not, satisfied the conditions of registration as stated in the Notice of Registration for Rozol Prairie Dog Bait, EPA Reg. No. 7173-286, dated May 13, 2009.

Thank you for your attention to this matter.

Sincerely,

Thomas Schmit
Manager of Regulatory Affairs
Liphatech, Inc.
schmitt@liphatech.com
(414) 410-7230

Re: [redacted]

Dan Peacock to: John Hebert 06/18/2009 09:02 AM

Cc: Jean Holmes, Bill Jacobs

John,

[redacted]

Internal deliberative information

[redacted]

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

John Hebert dan - [redacted] 06/17/2009 10:27:41 PM

From: John Hebert/DC/USEPA/US
To: Dan Peacock/DC/USEPA/US@EPA
Date: 06/17/2009 10:27 PM
Subject: Re: [redacted]

dan - [redacted]

-----Dan Peacock/DC/USEPA/US wrote: -----

To: Jean Holmes/DC/USEPA/US@EPA
From: Dan Peacock/DC/USEPA/US
Date: 06/17/2009 09:13AM
cc: Christina Swartz/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA
Subject: [redacted]

Internal Deliberations Do Not FOIA

Dear Jeannie,

[redacted]

Internal deliberative information

[redacted]

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

[redacted]

Internal deliberative information

Re: Fw[redacted]

Dan Peacock to: John Hebert 06/18/2009 12:53 PM

Cc: Jean Holmes

John,

[redacted]

Internal deliberative information

[redacted]

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

John Hebert dan - [redacted] 06/17/2009 10:58:41 PM

From: John Hebert/DC/USEPA/US
To: Dan Peacock/DC/USEPA/US@EPA
Date: 06/17/2009 10:58 PM
Subject: Re: F[redacted]

[redacted]

john
-----Dan Peacock/DC/USEPA/US wrote: -----

To: John Hebert/DC/USEPA/US@EPA
From: Dan Peacock/DC/USEPA/US
Date: 06/15/2009 04:11PM
cc: Bill Jacobs/DC/USEPA/US@EPA
Subject: Fw: [redacted]

John,

[redacted]

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Internal deliberative information

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

----- Forwarded by Dan Peacock/DC/USEPA/US on 06/15/2009 03:51 PM -----

From: Dan Peacock/DC/USEPA/US

To: Jean Holmes/DC/USEPA/US@EPA

Date: 06/15/2009 03:37 PM

Subject: [redacted]

Internal Deliberation Do Not FOIA

Jeannie,

[redacted]

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

Internal deliberative information

Re: [redacted]

Dan Peacock to: John Hebert 06/18/2009 01:03 PM

Cc: Jean Holmes, Bill Jacobs

[redacted]

John,

[redacted]

Internal deliberative information

[redacted]

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

John Hebert dan - [redacted] 06/17/2009 10:27:41 PM

From: John Hebert/DC/USEPA/US
To: Dan Peacock/DC/USEPA/US@EPA
Date: 06/17/2009 10:27 PM
Subject: [redacted]

[redacted]

-----Dan Peacock/DC/USEPA/US wrote: -----

To: Jean Holmes/DC/USEPA/US@EPA
From: Dan Peacock/DC/USEPA/US
Date: 06/17/2009 09:13AM
cc: Christina Swartz/DC/USEPA/US@EPA, Ray Kent/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA
Subject: [redacted]

Internal Deliberations Do Not FOIA

Dear Jeannie,

[redacted]

Internal deliberative information

[redacted]

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

[redacted]

Internal deliberative information

Nancy Golden 703-358-2077
Jeannie Holmes - 605-0211

5-12225

Fw: 7173-286, Heads Up on Change to be Requested on Endangered Species Considerations Section of Label

Dan Peacock to: Jean Holmes 06/15/2009 11:08 AM

Dear Jeannie,

- The registrant is waiting for our label revisions so we want to take advantage of this "window of opportunity" to get the best label text as possible for the "Interim Measures" for the "Endangered Species Considerations".
- If I cannot reach you, I may contact Nancy Golden directly so that she understands the importance of a timely response.

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

----- Forwarded by Dan Peacock/DC/USEPA/US on 06/15/2009 11:04 AM -----

From:	"Thomas Schmit" <SchmitT@liphatech.com>
To:	John Hebert/DC/USEPA/US@EPA, Dan Peacock/DC/USEPA/US@EPA
Cc:	"Rachel Callies" <CalliesR@liphatech.com>
Date:	06/12/2009 09:58 AM
Subject:	RE: 7173-286, Heads Up on Change to be Requested on Endangered Species Considerations Section of Label

John and Dan -

As I discussed with John last night, we want to submit a revised label and have a "clean" stamped label with this revision to the endangered species language.
Please send up the required change ASAP and we will submit the revised label to you promptly.

Our label submission will also contain a small revision, so that the word "hand" is not part of the "application Method" description. As we discussed, there are appropriate mechanical bait dispensers that can be used to place bait into a prairie dog burrow, as demonstrated in our efficacy study. Therefore, we will remove any reference to "hand" application.

Please send use the endangered species language

change ASAP

Thanks -
Tom Schmit
Liphatech, Inc.

From: Dan Peacock <Peacock.Dan@epamail.epa.gov>
Date: Thu, 11 Jun 2009 09:27:59 -0400
To: Rachael Callies <calliesr@liphatech.com>
Cc: Thomas Schmit <SchmitT@liphatech..com>, <Hebert.John@epamail.epa.gov>
Subject: 7173-286, Heads Up on Change to be Requested on Endangered Species Considerations Section of Label

Rachel,

After we registered this product, the USFWS informed us that portions of your approved Endangered Species Consideration section are out-of-date.
They are working on providing us with revised wording that we will forward to you as soon as we receive it, hopefully only a matter of days, at most.
Having the correct information on the label will help mitigation any adverse effects of the product to endangered species.

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

------ End of Forwarded Message

Kill Farewell EFED

Jeannie Holmes 605-0211

RE: 7173-286, Heads Up on Change to be Requested on Endangered Species Considerations Section of Label

Dan Peacock to: Thomas Schmit 06/15/2009 08:44 AM

Dear Mr. Schmit,

will do

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

"Thomas Schmit" John and Dan - 06/12/2009 09:58:09 AM

From: "Thomas Schmit" <SchmitT@liphatech.com>
To: John Hebert/DC/USEPA/US@EPA, Dan Peacock/DC/USEPA/US@EPA
Cc: "Rachel Callies" <CalliesR@liphatech.com>
Date: 06/12/2009 09:58 AM
Subject: RE: 7173-286, Heads Up on Change to be Requested on Endangered Species Considerations Section of Label

John and Dan -

As I discussed with John last night, we want to submit a revised label and have a "clean" stamped label with this revision to the endangered species language.
Please send up the required change ASAP and we will submit the revised label to you promptly.

Our label submission will also contain a small revision, so that the word "hand" is not part of the "application Method" description. As we discussed, there are appropriate mechanical bait dispensers that can be used to place bait into a prairie dog burrow, as demonstrated in our efficacy study. Therefore, we will remove any reference to "hand" application.

Please send use the endangered species language change ASAP

Thanks -
Tom Schmit
Liphatech, Inc.

From: Dan Peacock <Peacock.Dan@epamail.epa.gov>
Date: Thu, 11 Jun 2009 09:27:59 -0400
To: Rachael Callies <calliesr@liphatech.com>
Cc: Thomas Schmit <SchmitT@liphatech..com>, <Hebert.John@epamail.epa.gov>
Subject: 7173-286, Heads Up on Change to be Requested on Endangered Species Considerations Section of Label

Rachel,

After we registered this product, the USFWS informed us that portions of your approved Endangered Species Consideration section are out-of-date.
They are working on providing us with revised wording that we will forward to you as soon as we receive it, hopefully only a matter of days, at most.
Having the correct information on the label will help mitigation any adverse effects of the product to endangered species.

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

------ End of Forwarded Message

Fw: 7173-286, Heads Up on Change to be Requested on Endangered Species Considerations Section of Label

Dan Peacock to: Jean Holmes 06/11/2009 09:35 AM

Cc: John Hebert

Dear Jeannie,

- Please let me know ASAP when you get the revised Endangered Species Considerations text so that we can forward the revision to the registrant, LiphaTech.
- If possible, please check today with FWS to see if they could provide the information today.
- The next opportunity to communicate with the company will be next Monday.
- There is a greater chance of getting the correct text on the label if we any provide the revised label sooner rather than later.

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

----- Forwarded by Dan Peacock/DC/USEPA/US on 06/11/2009 09:28 AM -----

From:	Dan Peacock/DC/USEPA/US
To:	CalliesR@liphatech.com
Cc:	"Thomas Schmit" <SchmitT@liphatech..com>, John Hebert/DC/USEPA/US@EPA
Date:	06/11/2009 09:27 AM
Subject:	7173-286, Heads Up on Change to be Requested on Endangered Species Considerations Section of Label

[Did Mr. Schmit change his E-Mail address? The first attempt to send it to the above address to me was "undeliverable". Please forward and let me know if his address has changed. Thanks.]

Rachel,

- After we registered this product, the USFWS informed us that portions of your approved Endangered Species Consideration section are out-of-date.
- They are working on providing us with revised wording that we will forward to you as soon as we receive it, hopefully only a matter of days, at most.
- Having the correct information on the label will help mitigation any adverse effects of the product to endangered species.

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029

E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

Internal deliberative information

Re: Fw: chloropachinone sect 3?
Jean Holmes to: Dan Peacock 06/10/2009 03:30 PM
Cc: John Hebert, William Erickson, Tom Bailey, Meredith Laws

History: This message has been forwarded.

Hi Dan,

[redacted]

Dan Peacock | Dear Nancy, We discussed your request internal... | 06/04/2009 09:39:01 AM

From: Dan Peacock/DC/USEPA/US
To: Nancy_Golden@fws.gov
Cc: John Hebert/DC/USEPA/US@EPA, Jean Holmes/DC/USEPA/US@EPA
Date: 06/04/2009 09:39 AM
Subject: Re: Fw: chloropachinone sect 3?

Dear Nancy,

- We discussed your request internally in the Insecticide-Rodenticide Branch of the Registration Division on information on the Endangered Species "Interim Measures" pamphlets.
- Our management would prefer that you communicate directly with our Environmental Fate and Effects Division (EFED), who would know the most about the history and status of these pamphlets.
- Your EFED contact would be Ms. Jean Holmes (703-605-0211)

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

Nancy_Golden | Can you also send information on the Endanage... | 06/01/2009 10:47:26 AM

Re: Fw: 7173-286 Notice of Registration and the Endangered Species "Interim Measures" Pamphlet for Black-footed Ferrets

Jean Holmes to: Dan Peacock 06/03/2009 02:56 PM
Cc: Bill Jacobs, John Hebert, William Erickson

Hi Dan,

I am sorry that I am just getting back with you (meetings all day ((tears)). I agree, maybe we should all get together for a few minutes to discuss this issue. Do you want me to set up a meeting?

Dan Peacock | Jean and Bill, Jean, Thanks for your phone mes... | 06/03/2009 09:03:07 AM

From: Dan Peacock/DC/USEPA/US
To: Jean Holmes/DC/USEPA/US@EPA, William Erickson/DC/USEPA/US@EPA
Cc: Bill Jacobs/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA
Date: 06/03/2009 09:03 AM
Subject: Fw: 7173-286 Notice of Registration and the Endangered Species "Interim Measures" Pamphlet for Black-footed Ferrets

Jean and Bill,

- Jean, Thanks for your phone message.
- Here is what Bill Jacobs sent me.
- Perhaps, we need to meet on this one to determine the origin and status of the "Interim Measures".
- In the past both EFED and FEAD have had responsibility on endangered species.
- RD has required label text on the subject in the past. We want label references to endangered species and an "Interim Measures" pamphlet to be accurate and reflect current Agency policy.

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

----- Forwarded by Dan Peacock/DC/USEPA/US on 06/03/2009 08:53 AM -----

From: Bill Jacobs/DC/USEPA/US
To: Dan Peacock/DC/USEPA/US@EPA
Date: 06/02/2009 11:58 AM
Subject: Re: Fw: 7173-286 Notice of Registration and the Endangered Species "Interim Measures" Pamphlet for Black-footed Ferrets

[redacted]

Internal deliberative information

[redacted]

Dan Peacock Bill, [redacted] 06/02/2009 09:00:57 AM

Internal deliberative information

Golden/ARL/R9/FWS/DOI]  pic05447.gif

Fw: 7173-286 Notice of Registration and the Endangered Species "Interim Measures" Pamphlet for Black-footed Ferrets

Dan Peacock to: Jean Holmes, William Erickson 06/03/2009 09:03 AM

Cc: Bill Jacobs, John Hebert

Jean and Bill,

- Jean, Thanks for your phone message.
- Here is what Bill Jacobs sent me.
- Perhaps, we need to meet on this one to determine the origin and status of the "Interim Measures".
- In the past both EFED and FEAD have had responsibility on endangered species.
- RD has required label text on the subject in the past. We want label references to endangered species and an "Interim Measures" pamphlet to be accurate and reflect current Agency policy.

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

----- Forwarded by Dan Peacock/DC/USEPA/US on 06/03/2009 08:53 AM -----

From:	Bill Jacobs/DC/USEPA/US
To:	Dan Peacock/DC/USEPA/US@EPA
Date:	06/02/2009 11:58 AM
Subject:	Re: Fw: 7173-286 Notice of Registration and the Endangered Species "Interim Measures" Pamphlet for Black-footed Ferrets

[redacted]

Dan Peacock Bill, [redacted] 06/02/2009 09:00:57 AM

From:	Dan Peacock/DC/USEPA/US
To:	Bill Jacobs/DC/USEPA/US@EPA
Date:	06/02/2009 09:00 AM

Internal deliberative information

Subject: Fw [redacted]

Bill,

[redacted]

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

----- Forwarded by Dan Peacock/DC/USEPA/US on 06/02/2009 08:57 AM -----

From: Dan Peacock/DC/USEPA/US
To: Jean Holmes/DC/USEPA/US@EPA
Date: 06/02/2009 08:54 AM
Subject: Fw: [redacted]

Jeannie,

[redacted]

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Internal deliberative information

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

----- Forwarded by Dan Peacock/DC/USEPA/US on 06/02/2009 08:30 AM -----

From:	Dan Peacock/DC/USEPA/US
To:	Nancy_Golden@fws.gov
Cc:	John Hebert/DC/USEPA/US@EPA
Date:	06/01/2009 01:50 PM
Subject:	Fw: 7173-286 Notice of Registration and the Endangered Species "Interim Measures"

Dear Ms. Golden,

I have attached our Notice of Registration, with comments, for this product below.

I do not have a copy of the pamphlet, myself.
However, according to the label, which our fish and wildlife risk assessor reviewed, the "**ENDANGERED SPECIES CONSIDERATIONS**" section states, in part:

> Do not use this product within prairie dog towns in the range of the black-footed ferret without first contacting endangered species specialists at a U.S. Fish and Wildlife Service office. Applicators may obtain information regarding the occurrence of endangered species and use limitations for this product by calling EPA's "Endangered Species Hotline" at 1-800-447-3813 to obtain an "Interim Measures" pamphlet for your county.

If you need additional information, please contact me.

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

Re: Fw: 7173-286 Notice of Registration and the Endangered Species "Interim Measures"

Nancy_Golden to: Dan Peacock 06/01/2009 02:34 PM

Cc: John Hebert

History: This message has been replied to.

Internal deliberative information

Dan,

[redacted]

Thanks,
Nancy

****

Nancy Golden
Division of Environmental Quality
U.S. Fish & Wildlife Service
4401 N. Fairfax Drive, Suite 820
Arlington, VA 22203
(703) 358-2077
(703) 358-1800 fax
email: Nancy_Golden@fws.gov

Peacock.Dan@epamail.epa.gov

Peacock.Dan @epamail.epa.gov

06/01/2009 01:50 PM

ToNancy_Golden@fws.gov

ccHebert.John@epamail.epa.gov

SubjectFw: 7173-286 Notice of Registration and the Endangered Species "Interim Measures"

Dear Ms. Golden,

I have attached our Notice of Registration, with comments, for this
product below.

I do not have a copy of the pamphlet, myself.
However, according to the label, which our fish and wildlife risk assessor reviewed, the "ENDANGERED SPECIES CONSIDERATIONS" section
states, in part:

Do not use this product within prairie dog towns in the range of the
black-footed ferret without first contacting endangered species
specialists at a U.S. Fish and Wildlife Service office. Applicators
may obtain information regarding the occurrence of endangered species
and use limitations for this product by calling EPA's "Endangered
Species Hotline" at 1-800-447-3813 to obtain an "Interim Measures"
pamphlet for your county.

If you need additional information, please contact me.

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide
Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW,
Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration
Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington,
VA 22202

Please open the attached document. This document was digitally sent to
you using an HP Digital Sending device.(See attached file: [Untitled].pdf)
[attachment "[Untitled].pdf" deleted by Nancy

Re: Fw: chloropachinone sect 3?
Nancy_Golden to: John Hebert 06/01/2009 10:47 AM
Cc: Dan Peacock

History: This message has been replied to and forwarded.

Can you also send information on the Endanagered Species "Interim Measures" pamphlets. I'm not at all familiar with those and as you know, FWS has expressed concern for T&E species for this product.

Thanks, Nancy

Hebert.John@epamail.epa.gov

Hebert.John@epamail.epa.gov
05/29/2009 07:53 PM

ToPeacock.Dan@epamail.epa.gov
ccNancy_Golden@fws.gov
SubjectFw: chloropachinone sect 3?

Dan - On Monday, can you please email Nancy a copy of the label/reg notice for Lipha's prairie dog product? Thanks.

john

-----Forwarded by John Hebert/DC/USEPA/US on 05/29/2009 07:51PM -----

To: John Hebert/DC/USEPA/US@EPA
From: Nancy_Golden@fws.gov
Date: 05/29/2009 11:50AM
Subject: chloropachinone sect 3?

Hi John,

We heard from one of the state agencies that there was a new chlorophacinone Sect 3 for use on black-tailed prairie dogs, but haven't seen anything about it and haven't been able to turn up a label. Do you have a label that you can send us to look at?

Thanks, Nancy

****

Nancy Golden
Division of Environmental Quality
U.S. Fish & Wildlife Service
4401 N. Fairfax Drive, Suite 820
Arlington, VA 22203
(703) 358-2077
(703) 358-1800 fax
email: Nancy_Golden@fws.gov


pic18467.gif

[redacted]

Dan Peacock to: John Hebert 06/15/2009 04:11 PM
Cc: Bill Jacobs
Bcc: William Erickson

John,

[redacted]

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

----- Forwarded by Dan Peacock/DC/USEPA/US on 06/15/2009 03:51 PM -----

From: Dan Peacock/DC/USEPA/US
To: Jean Holmes/DC/USEPA/US@EPA
Date: 06/15/2009 03:37 PM
Subject: [redacted]

Internal Deliberation Do Not FOIA

Jeannie,

[redacted]

Internal deliberative information

[redacted]

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

Internal deliberative information

[redacted] Dan Peacock to: Jean Holmes 06/15/2009 03:37 PM

Internal Deliberation Do Not FOIA

Jeannie,

[redacted]

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

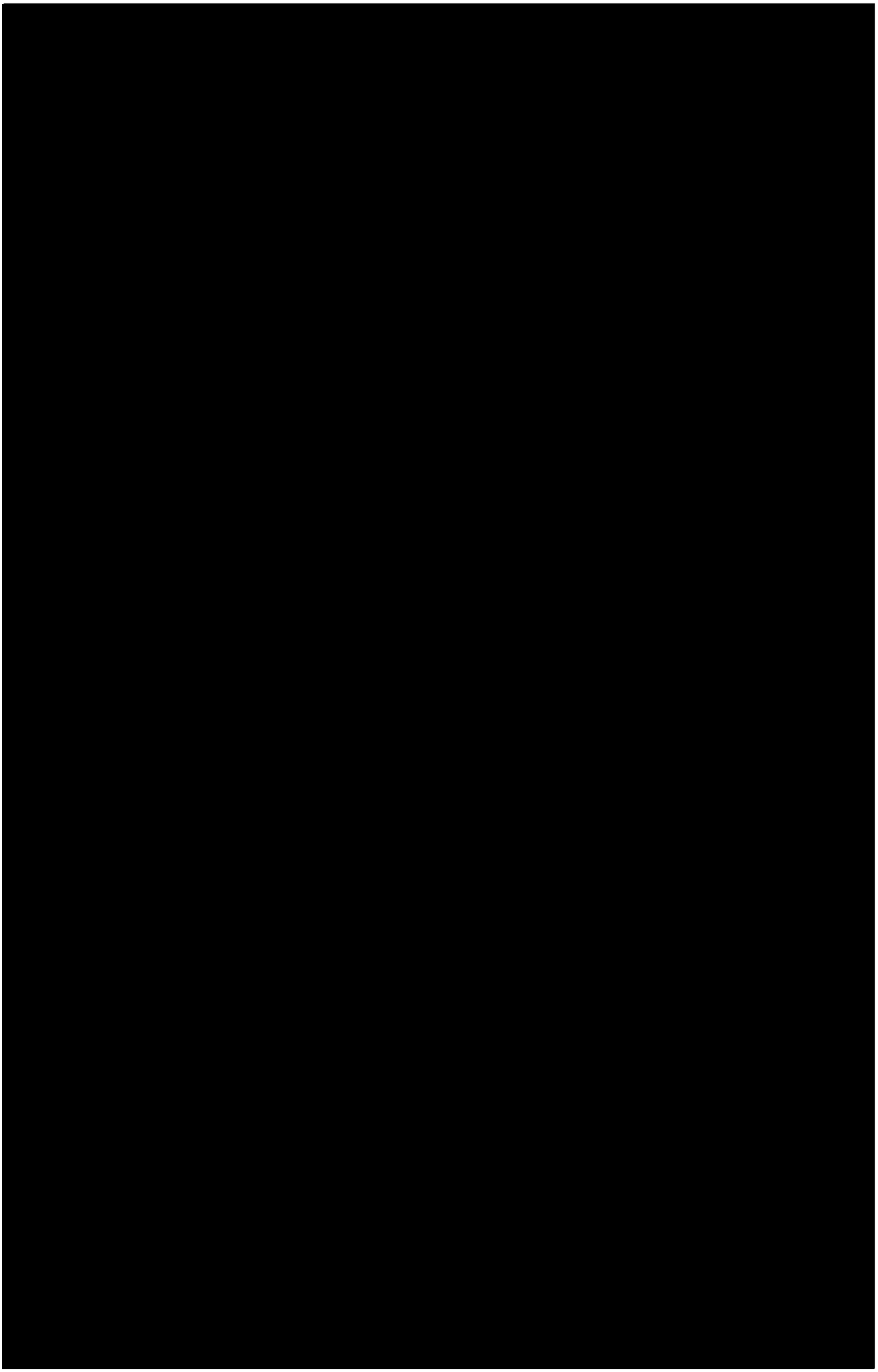
Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

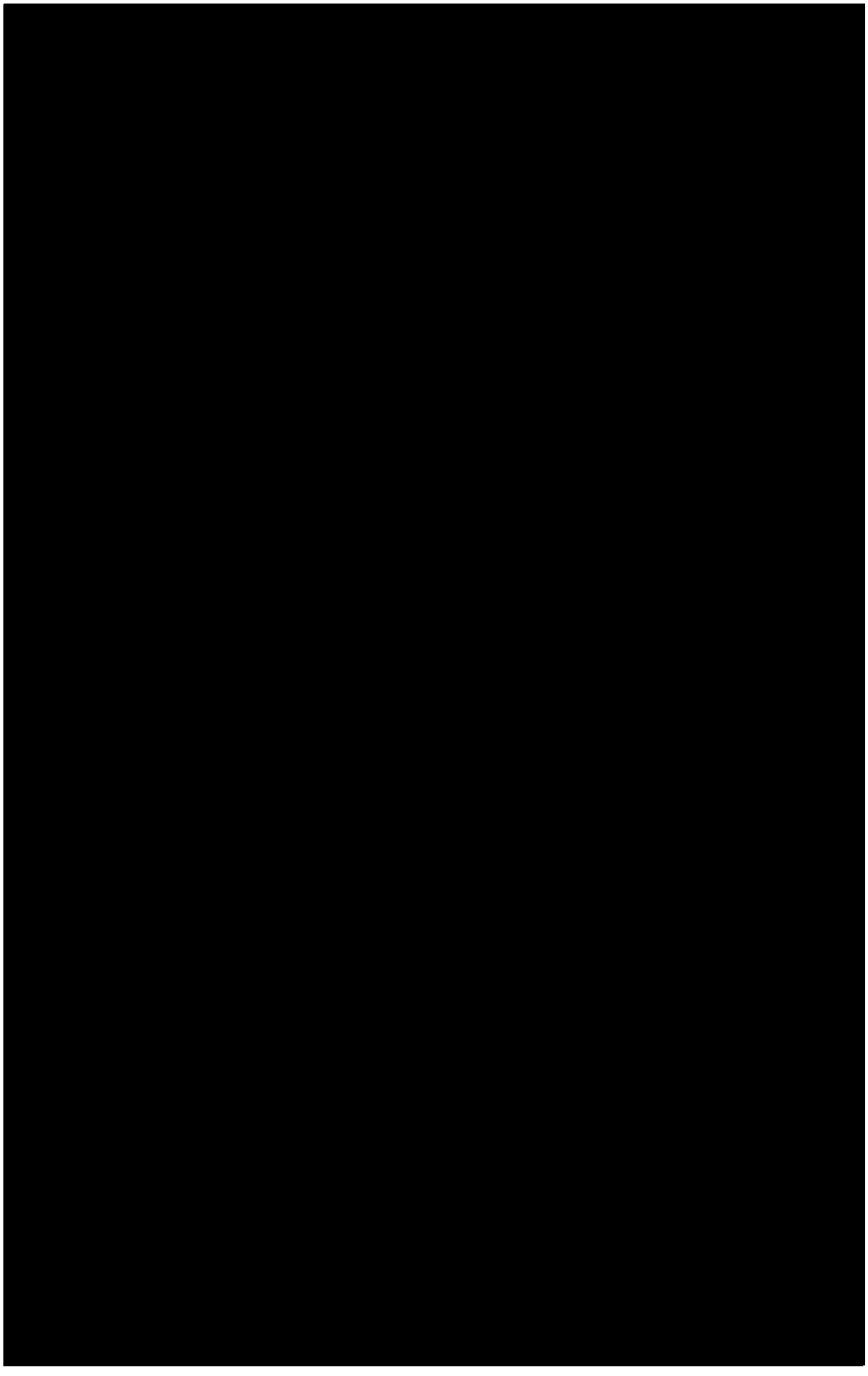
Internal deliberative information

[redacted]

Internal deliberative information

Internal deliberative information





From: Dan Peacock <Peacock.Dan@epamail.epa.gov>
Date: Thu, 11 Jun 2009 09:27:59 -0400
To: Rachael Callies <calliesr@liphatech.com>
Cc: Thomas Schmit <SchmitT@liphatech..com>, <Hebert.John@epamail.epa.gov>
Subject: 7173-286, Heads Up on Change to be Requested on Endangered Species Considerations Section of Label

Rachel,

After we registered this product, the USFWS informed us that portions of your approved Endangered Species Consideration section are out-of-date.
They are working on providing us with revised wording that we will forward to you as soon as we receive it, hopefully only a matter of days, at most.
Having the correct information on the label will help mitigation any adverse effects of the product to endangered species.

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

------ End of Forwarded Message

RE: 7173-286, Heads Up on Change to be Requested on Endangered Species Considerations Section of Label
Thomas Schmit
to:
John Hebert, Dan Peacock
06/12/2009 09:58 AM
Cc:
"Rachel Callies"
Show Details

History: This message has been replied to and forwarded.
John and Dan -

As I discussed with John last night, we want to submit a revised label and have a "clean" stamped label with this revision to the endangered species language.
Please send up the required change ASAP and we will submit the revised label to you promptly.

Our label submission will also contain a small revision, so that the word "hand" is not part of the "application Method" description. As we discussed, there are appropriate mechanical bait dispensers that can be used to place bait into a prairie dog burrow, as demonstrated in our efficacy study. Therefore, we will remove any reference to "hand" application.

Please send use the endangered species language change ASAP

Thanks -
Tom Schmit
Liphatech, Inc.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 4, 2009

[State Regulatory Authority, CO, KS, NE, OK, TX, WY]
[Address]

Attention: [Regulatory Contact]

Subject Rozol Prairie Dog Bait
EPA SLN Reg. No. [number]
EPA Reg. No. [parent registration number]
Your Notification of [date]

Purpose This submission of [Date] notifies us of your approval of a Special Local Need (SLN) registration under section 24(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to amend a Federal registration to add the new use to control black-tailed prairie dogs.

Section 3 Approval On [insert date], LiphaTech submitted an application to register the same new use under section 3 of FIFRA and, once registered, cancel its SLN registrations, such as this one. On May 13, 2009, the Agency approved this request. We have enclosed a copy of this Notice with this letter.

Cancellatiion of SLNs Note that one condition of registration is that, within 30 days of the approval of registration, LiphaTech must submit a request to EPA and the states with SLN registrations with Chlorophacinone as an active ingredient and black-tailed prairie dogs as a pest, including [list of SLN registrations], to cancel such registrations voluntarily.

Questions If you have questions about this letter, please contact me at 703-305-5407 (phone); 703-305-6596 (fax); or peacock.dan@epa.gov (E-Mail).

Sincerely,

Daniel B. Peacock, Biologist
Insecticide-Rodenticide Branch
Registration Division (7504C)

Enclosures Notice of Registration, Rozol Prairie Dog Bait, EPA Reg. No. 7173-286
Copy of your SLN label

File Location Dan Peacock, Flash Drive, 16gb, E:\4G Dan\Doc\Word\Chlorophacinone\7173-EIA, 286\Ltrs to States w prairie dog use\generic Ltr to States w SLNs for pr dogs, 6-4-2009.doc

Fw: 7173-286 Notice of Registration and the Endangered Species "Interim Measures"

Dan Peacock to: Nancy_Golden 06/01/2009 01:50 PM

Cc: John Hebert

Dear Ms. Golden,

I have attached our Notice of Registration, with comments, for this product below.

I do not have a copy of the pamphlet, myself.
However, according to the label, which our fish and wildlife risk assessor reviewed, the "**ENDANGERED SPECIES CONSIDERATIONS**" section states, in part:

> Do not use this product within prairie dog towns in the range of the black-footed ferret without first contacting endangered species specialists at a U.S. Fish and Wildlife Service office. Applicators may obtain information regarding the occurrence of endangered species and use limitations for this product by calling EPA's "Endangered Species Hotline" at 1-800-447-3813 to obtain an "Interim Measures" pamphlet for your county.

If you need additional information, please contact me.

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

[Untitled].pdf

Fw: chloropachinone sect 3?
John Hebert
to:
Dan Peacock
05/29/2009 07:53 PM
Cc:
Nancy_Golden
Show Details

Dan - On Monday, can you please email Nancy a copy of the label/reg notice for Lipha's prairie dog product? Thanks.

john

-----Forwarded by John Hebert/DC/USEPA/US on 05/29/2009 07:51PM -----

To: John Hebert/DC/USEPA/US@EPA
From: Nancy_Golden@fws.gov
Date: 05/29/2009 11:50AM
Subject: chloropachinone sect 3?

Hi John,

We heard from one of the state agencies that there was a new chlorophacinone Sect 3 for use on black-tailed prairie dogs, but haven't seen anything about it and haven't been able to turn up a label. Do you have a label that you can send us to look at?

Thanks, Nancy

****
Nancy Golden
Division of Environmental Quality
U.S. Fish & Wildlife Service
4401 N. Fairfax Drive, Suite 820

Arlington, VA 22203
(703) 358-2077
(703) 358-1800 fax
email: Nancy_Golden@fws.gov

Re: Fw: chloropachinone sect 3?
Nancy_Golden to: John Hebert 06/01/2009 10:47 AM
Cc: Dan Peacock

Can you also send information on the Endanagered Species "Interim Measures" pamphlets. I'm not at all familiar with those and as you know, FWS has expressed concern for T&E species for this product.

Thanks, Nancy

Hebert.John@epamail.epa.gov

Hebert.John@epamail.epa.gov

05/29/2009 07:53 PM

ToPeacock.Dan@epamail.epa.gov

ccNancy_Golden@fws.gov

SubjectFw: chloropachinone sect 3?

Dan - On Monday, can you please email Nancy a copy of the label/reg notice for Lipha's prairie dog product? Thanks.

john

-----Forwarded by John Hebert/DC/USEPA/US on 05/29/2009 07:51PM -----

To: John Hebert/DC/USEPA/US@EPA
From: Nancy_Golden@fws.gov
Date: 05/29/2009 11:50AM
Subject: chloropachinone sect 3?

Hi John,

We heard from one of the state agencies that there was a new chlorophacinone Sect 3 for use on black-tailed prairie dogs, but haven't seen anything about it and haven't been able to turn up a label. Do you have a label that you can send us to look at?

Thanks, Nancy

****

Nancy Golden
Division of Environmental Quality

To: Nancy_Golden@fws.gov
Cc: John Hebert/DC/USEPA/US@EPA, Jean Holmes/DC/USEPA/US
Bcc:
Subject: Re: Fw: chloropachinone sect 3?

Dear Nancy,

- We discussed your request internally in the Insecticide-Rodenticide Branch of the Registration Division on information on the Endangered Species "Interim Measures" pamphlets.
- Our management would prefer that you communicate directly with our Environmental Fate and Effects Division (EFED), who would know the most about the history and status of these pamphlets.
- Your EFED contact would be Ms. Jean Holmes (703-605-0211)

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

Nancy_Golden | Can you also send information on the Endanage... | 06/01/2009 10:47:26 AM

From: Nancy_Golden@fws.gov
To: John Hebert/DC/USEPA/US@EPA
Cc: Dan Peacock/DC/USEPA/US@EPA
Date: 06/01/2009 10:47 AM
Subject: Re: Fw: chloropachinone sect 3?

Can you also send information on the Endanagered Species "Interim Measures" pamphlets. I'm not at all familiar with those and as you know, FWS has expressed concern for T&E species for this product.

Thanks, Nancy

Hebert.John@epamail.epa.gov

Hebert.John@epamail.epa.gov

05/29/2009 07:53 PM

ToPeacock.Dan@epamail.epa.gov

ccNancy_Golden@fws.gov

SubjectFw: chloropachinone sect 3?

Dan - On Monday, can you please email Nancy a copy of the label/reg notice for Lipha's prairie dog product? Thanks.

john

-----Forwarded by John Hebert/DC/USEPA/US on 05/29/2009 07:51PM -----

To: John Hebert/DC/USEPA/US@EPA
From: Nancy_Golden@fws.gov
Date: 05/29/2009 11:50AM
Subject: chloropachinone sect 3?

Hi John,

We heard from one of the state agencies that there was a new chlorophacinone Sect 3 for use on black-tailed prairie dogs, but haven't seen anything about it and haven't been able to turn up a label. Do you have a label that you can send us to look at?

Thanks, Nancy

****

Nancy Golden
Division of Environmental Quality
U.S. Fish & Wildlife Service
4401 N. Fairfax Drive, Suite 820
Arlington, VA 22203
(703) 358-2077
(703) 358-1800 fax
email: Nancy_Golden@fws.gov


pic18467.gif

Fw: 7173-286 Notice of Registration and the Endangered Species "Interim Measures" Pamphlet for Black-footed Ferrets

John Hebert to: Dan Peacock 06/03/2009 02:58 PM

dan - please wait to respond. meredith may want to take RD out of this and have FWS talk to EFED directly.

john

----- Forwarded by John Hebert/DC/USEPA/US on 06/03/2009 02:57 PM -----

From:	Jean Holmes/DC/USEPA/US
To:	Dan Peacock/DC/USEPA/US@EPA
Cc:	Bill Jacobs/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA, William Erickson/DC/USEPA/US@EPA
Date:	06/03/2009 02:56 PM
Subject:	Re: Fw: 7173-286 Notice of Registration and the Endangered Species "Interim Measures" Pamphlet for Black-footed Ferrets

Hi Dan,

I am sorry that I am just getting back with you (meetings all day ((tears)). I agree, maybe we should all get together for a few minutes to discuss this issue. Do you want me to set up a meeting?

Dan Peacock Jean and Bill, Jean, Thanks for your phone mes... 06/03/2009 09:03:07 AM

From:	Dan Peacock/DC/USEPA/US
To:	Jean Holmes/DC/USEPA/US@EPA, William Erickson/DC/USEPA/US@EPA
Cc:	Bill Jacobs/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA
Date:	06/03/2009 09:03 AM
Subject:	Fw: 7173-286 Notice of Registration and the Endangered Species "Interim Measures" Pamphlet for Black-footed Ferrets

Jean and Bill,

- Jean, Thanks for your phone message.
- Here is what Bill Jacobs sent me.
- Perhaps, we need to meet on this one to determine the origin and status of the "Interim Measures".
- In the past both EFED and FEAD have had responsibility on endangered species.
- RD has required label text on the subject in the past. We want label references to endangered species and an "Interim Measures" pamphlet to be accurate and reflect current Agency policy.

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

[redacted]

Internal deliberative information